CONSUMERS' KNOWLEDGE AND USE OF PARACETAMOL (ACETAMINOPHEN) IN OVER-THE-COUNTER MEDICATIONS

A Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY,

CHENNAI- 600 032

In partial fulfilment of the award of the degree of

MASTER OF PHARMACY

IN

Branch-VII –PHARMACY PRACTICE

Submitted by

Name: MUHAMMED SHARKY .A

REG.No.261640206

Under the Guidance of

Dr. N. VENKATESWARAMURTHY, M.Pharm., PhD,

DEPARTMENT OF PHARMACY PRACTICE

J.K.K. NATTRAJA COLLEGE OF PHARMACY

KUMARAPALAYAM – 638183

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CERTIFICATES

EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled **"Consumers' knowledge and use of Paracetamol (acetaminophen) in over-the-counter Medications"** submitted by the student bearing **[REG.No.261640206]** to **"The Tamil Nadu Dr. M.G.R. Medical University"**, Chennai, in partial fulfillment for the award of Degree of **Master of Pharmacy** in **Pharmacy Practice** was evaluated by us during the examination held on.....

Internal Examiner **External Examiner**

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Dr.R. SAMBATH KUMAR, M.Pharm,Ph.D.,
Principal,
J.K.K.Nattraja College of Pharmacy,
Kumarapalayam-638 183.

Dr.N.VENKATESWARAMURTHY, M.Pharm,Ph.D.,
Professor and Guide,
Department of Pharmacy Practice,
J.K.K.Nattraja College of Pharmacy,
Kumarapalayam-638 183.

Place: Kumarapalayam
Date:

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Place: Kumarapalayam
Date:

Dr.R. SAMBATH KUMAR, M.Pharm,Ph.D.,
Professor & Principal,
J.K.K.Nattraja College of Pharmacy.
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Place: Kumarapalayam
Date:

Dr.N.VENKATESWARAMURTHY, M.Pharm,Ph.D.,
Professor and Head,
Department of Pharmacy Practice,
J.K.K.Nattraja College of Pharmacy.
Kumarapalayam-638 183.

DECLARATION

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I do hereby declared that the dissertation **"Consumers' knowledge and use of Paracetamol (acetaminophen) in over-the-counter Medications",** submitted to "**The Tamil Nadu Dr. M.G.R Medical University"**, Chennai, for the partial fulfillment of the degree of **Master of Pharmacy** in **Pharmacy Practice,** It is a bonafide research work has been carried out by me during the academic year 2016-2017, under the guidance and supervision of **Dr. N.Venkateswaramurthy, M.Pharm., Ph.D.,** Professor, Head, Department of Pharmacy practice, J.K.K. Nattraja College of Pharmacy, Kumarapalayam.

I further declare that this work is original and this dissertation has not been submitted previously for the award of any other degree, diploma, associate ship and fellowship or any other similar title. The information furnished in this dissertation is genuine to the best of my knowledge.

Place: Kumarapalayam

Date:

Mr. MUHAMMED SHARKY .A

[REG.No.261640206]

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Mr. MUHAMMED SHARKY .A

[REG.No. 261640206]

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INTRODUCTION

1. INTRODUCTION

Self-medication is a major form of self-care.[1] It involves the use of medicinal products by the consumer to treat self recognized disorder, symptoms, recurrent disease or minor health problems.[2-4]It is independent of age for both males and females.[5] Medicines for self-medication are often called Over the Counter (OTC) drug, which are available without a Doctors prescription through pharmacies, mostly in the less developed countries.[6,7]

Recent development of the pharmaceutical companies contribute to a wide spread availability of OTC Medicine.[8] There is also the potential for misuse and abuse of such products.[9,10] A major problem of self medication with antimicrobials is the emergence of human pathogens resistance world wide particularly in developing countries, where antibiotics are often available without a prescription.[11]Its irrational use increases the risk of adverse events, bacterial infection, Hypersensitivity, Drug withdrawal symptoms and of masking disease which can delay correct diagnosis.[4,11-13]Self-medication is a global problem, 47.6% prevalence of self medication has been reported among the infant in Nigeria. Abdominal pain, constipation, fever and cough are the most common symptom of infants that that are frequently treated with self medication in Nigeria.[14] It is linked to perceived quality of a country's health care system, even in industrialized countries: many simple medications are available for routine use and are sold in Drug store and supermarket also.[15] Self-medication is a common practice and internationally has been reported as being on rise and can produce a good result and be a convenient practice for patient.[16,17] Self-medication particularly with antibiotics has been widely reported leading the WHO to call attention to the dangers of self medication as a cause of antibiotic resistance.[7,18-21] In country like India there is a wide range of drugs coupled with

inadequate health service result in increase proportion of drug used as a medication compared to prescribed drugs.[17,22,23]

WHY DO PEOPLE USE SELF MEDICATION?

Modern consumers (patients) wish to take a greater role in the maintenance of their own health and are often competent to manage (uncomplicated) chronic and recurrent illnesses (not merely short-term symptoms) after proper medical diagnosis and with only occasional professional advice, e.g. use of histamine H 2- receptor blocker, topical corticosteroid, antifungal and oral contraceptive. They are understandably unwilling to submit to the inconvenience of visiting a doctor for what they rightly feel they can manage for themselves, given adequate information.[24]Self-medication is very common and a number of reasons could be enumerated for it.[25,26] Urge of self-care, feeling of sympathy towards family members in sickness, lack of health services, poverty, ignorance, misbelieves, extensive advertisement and availability of drugs in other than drug shops are responsible for growing trend of self-medication.[27]

According to a report of self-medication,[28] Male (35.48%) and female (15.56%) used Self Medication due to the lack of time, 32.26% male and 26.67% female used self medication due to High consultant Fee of Physician, 29.03% male and 11.11% female wants Quick relief, 3.33 % male and 24.44% female believe in Ayurveda, There are some cases of female (6.67%) in which there is no family support hence they uses self medication, 15.56% female used self-medication due to unable to walk. There are some other reasons like wider availability of medicine, greater choice of treatments, ease of access,[29] an active role in his/ her own health care and self reliance in preventing or reliving miner symptoms or condition, ailment was minor and financial constraint.[30]

WHY DO PARENTS USE SELF MEDICATION TO THEIR CHILDREN?

Parents who self-medicate their children are more likely than adults who medicate themselves to say they do so because the illness isn't serious enough to warrant a visit to the doctor (88% parents of children under 18 vs. 78% adults in general).[31]

1. Parents are also more likely than adults in general to believe that non-prescription medications are just as effective as prescription drugs.

2. Adults who self-medicate are more likely than parents who medicate their children to say they do so in order to save money (70% adults in general vs. 57% parents of children under 18) or avoid a trip to doctor's office (78% adults in general vs. 65% parents of children under 18).

SELF MEDICATION: WORLD WIDE

The concept of self medication which encourages an individual to look after minor ailments with simple and effective remedies has been adopted worldwide.[33] People hold the view that medicine should be used in the event of any sickness or discomfort. In the United Kingdom where on the average 50% of health care takes place within the realm of self-medication.[2] Self-medication is very common now a days and it is being used worldwide.[34]

CONDITIONS TREATED BY SELF MEDICATION

There is a wide variety of conditions, in which OTC drugs are used.[16,32] Most commonly available OTC medications are pain killers, cough and cold remedies, anti-allergy medicines, vitamins and energy tonics. Although these medications are considered risk-free and useful for the treatment of common health problems, their excessive use can also

lead to serious side-effects and unfavorable reactions.[8] Generally Consumers tend to utilize private pharmacies rather than public facilities for self-medication.[7,35]

HOW DO PEOPLE GET INFORMATION FOR SELF MEDICATION?

There are various sources from where people get information[36] like, a pharmacist, Household members, product information leaflet, friends, relatives (not healthcare professionals) and advertisements.

ADVANTAGES & DISADVANTAGES OF SELF MEDICATION

Advantages:

Expected health benefit from self medication depends on perceived effectiveness of self-medication.[37]In a world of scarce government and in many countries scarce individual resources, responsible self medication should be a cornerstone of healthcare provision and health policy. Responsible self medication can:

1. Help to prevent and treat symptoms and ailments that do not require a doctor.

2. Reduce the pressure on medical services where health care personnel are insufficient.

3. Increase the availability of health care to populations living in rural or remote areas.

4. Enable patients to control their own chronic conditions.

These benefits translate into patient and consumer wellness and productivity, economic gain for employers, and cost savings to healthcare budgets through reduced medicine budget cost and reduced physician visits. These conditions aim at ensuring the safety of taking self medicated drugs. They include the following: the drugs used are those

indicated for conditions that are self recognizable; the user should know how to take or use the drugs; the effects and possible side effects of the drugs as well as ways of monitoring these side effects are well communicated to the user; possible interactions with other drugs is known by the user; duration of the course of the drugs is known by the user and, when the user must seek professional intervention.[38]

Disadvantages:

Modern medicine have become absorbed rapidly in to the local custom through out the world, their ubiquitous distribution, powerful marketing and poor control mean that they are used and misused for a wide range of applications.[39] Misuse is defined as using an OTC product for a legitimate medical reason but in higher doses or for a longer period than recommended, e.g. taking more of a painkiller than recommended to treat a headache. Reports have proven that Paracetamol, an antipyretic and analgesic in large doses can cause liver failure. Paracetamol toxicity is, by far, the most common cause of acute liver failure in both the United States and the United Kingdom. It is also not a very greatly advertised fact that coffee consumed with Paracetamol or too much of alcohol consumption in association with the drug usage, can cause unprecedented liver failure rates.[40,41]

Growth of OTC Sales in India: The sale of analgesic rises 15.8% in 2009 which was 10.7% in 2008. Vitamins, minerals and other supplements are increased by 8.8% from 8.2%. Gastrointestinal drugs rises up to 10.4% and other OTC drugs increased by 38.9 %.[42]

PAIN DRUGS IN OTC

In 1994, the Center for Drug Evaluation and Research of the FDA revised their policy on labeling indications for all OTC analgesic/antipyretic agents.[51] To be granted a generalized pam medication "for the temporary relief of occasional aches and pains," OTC analgesics must demonstrate efficacy (compared with placebo) in 22 adequate and well-controlled studies.

Appropriate models for this medication include dental postsurgical pam (oral surgery), sore throat pain, and muscle strains. To gain indications for headache or menstrual cramps (dysmenorrhea), single well-controlled clinical studies must demonstrate efficacy in each model. Finally, to obtain OTC labeling for antipyretics, effectiveness must be shown in both children and adults, since children are frequently treated for fever with OTC products despite restrictive labeling.

All of the products listed in Table I have met the FDA's requirements and have obtained indications for pain, headache, dysmenorrhea, and fever. One OTC proprietary analgesic combination (Excedrin Migraine) was the first to receive an indication for migraine. What is important at this stage is an analysis of how the various OTC analgesics/antipyretics compare with each other in clinical studies. Many of the published reports on chemical entities that have gained OTC approval have assessed single doses or daily regimens that exceed the approved OTC range.

Even major reviews of OTC analgesics in specific pain models are guilty of including these types of studies in their analyses.[52]In reality, a claim that 1 OTC analgesic works better than another should be supported by studies in which both products have been assessed at the OTC dosage ranges

Evidence suggests that the use of certain OTC drugs is causing significant harm. Studies have shown that consumers may misuse acetaminophen, a common ingredient in OTC analgesics as well as prescription products. Many authors view this increase in the personal responsibility of patients as something positive[53] but several concerns have arisen regarding adverse drug reactions (ADRs) caused by self-medication. For example, analgesics taken as self-medication have been described as harmful, particularly in elderly patients.[54] Additionally, a drug–drug interaction (DDI) between a self-medication and a prescribed medication might increase the risk for developing an ADR.[55,56]

Analgesics such as paracetamol (acetaminophen), aspirin, and other nonsteroidal anti-inflammatory drugs (NSAIDs) are becoming increasingly available over-the-counter (OTC) worldwide. In the India, United Kingdom, the Europe Union, and Australia, paracetamol, ibuprofen, and aspirin are available in OTC preparations. Some analgesics have adverse effects in therapeutic doses; all analgesics are toxic in overdose.[43]An ADR leading to hospital admission was defined, in accordance with World Health Organization (WHO) guidelines, as a ''response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function".[44] In terms of methodology, we used an approach similar to that of Olivier *et al*.[45] and so included formerly prescribed drugs taken without current medical advice in our definition of self-medication (OTC drugs). In addition to that, information regarding ADRs caused by self-medication also leading to hospitalization with a particular emphasis on both formerly prescribed drugs and OTC drugs.

Self-medication that is sometimes overlooked is that people may use a formerly prescribed medication at a later point in time, without informing their physician. Thus, although self-medication is defined as the use of non-prescription drugs (OTC drugs) by most authors,[46] a different definition that has been proposed includes the use of formerly prescribed drugs taken at a later time point without a physician's recommendation.[47] Patients' risk awareness is lower with respect to OTC drugs than for drugs prescribed by physicians.[48] Not surprisingly, a remarkable number of consumers take OTC drugs for longer and even in higher doses than recommended in the package insert without consulting a physician.[48,49] As all drugs have the potential for adverse reactions, it is of great interest to evaluate the safety profile of OTC drugs. However, there are few safety data available for OTC drugs. This may be due to several methodological difficulties regarding the assessment of drug exposure and ADRs. Prescription databases—which are widely used for analysing ADRs associated with Rx drug utilization—cannot be used for OTC drugs. Thus, pharmacy-centered studies are required, but a complete medication history is difficult to obtain in this setting. Non-recognition of OTC drugs as 'drugs' by patients, and incomplete medical histories taken by physicians, may contribute to uncertainties in evaluating OTC drug-related ADRs.[50]

Acetaminophen is the most commonly used medication. It can be used in both adult and pediatric populations and can be an effective analgesic and antipyretic to relieve symptoms associated with injury, viral and bacterial infections, and headaches.[57-59] Although considered safe when taken as recommended, liver toxicity can occur with doses greater than 4 g or when used in patients with preexisting liver dysfunction.[57,60] Acetaminophen toxicity is the most common cause of acute liver failure and is the most common reason for calls made to poison control centers.[58,60] It has been estimated that

overdose with acetaminophen leads to more than 56,000 emergency department visits, more than 2,600 hospitalizations, and approximately 400 deaths from acute liver failure every year. Acetaminophen is available in multiple dosage forms, including oral pills and liquids, suppositories, and even intravenous formulations in some hospitals. Because of its presence in so many different products, patients may not recognize which products contain acetaminophen. An estimated 15% of acute liver failure cases result from patients who unknowingly consumed multiple acetaminophen-containing preparations simultaneously and more than 100 deaths annually are caused by unintentional overdose.[58,59]

Food and Drug Administration (FDA) issued several recommendations for labeling of OTC pain relievers. In 2006, FDA proposed adding a new warning for liver damage and making the active ingredient more prominent on the packaging.[60] These changes were finalized in 2009 with some additional requirements.[61] The new regulations require the liver warning to be present on the immediate container and the outer carton labeling. In addition, a warning appears stating that patients should not use acetaminophen with warfarin and that they should ask a physician or pharmacist if they are unsure whether a medication contains acetaminophen. Examining the effect of these changes on patient knowledge of acetaminophen safety, dosing and identification is important.

Better identification of gaps in patient knowledge regarding the presence of acetaminophen in OTC medications is needed. This will facilitate development of interventions to increase patient safety, prevent overdoses and guide patients in obtaining appropriate care following an overdose.

PARACETAMOL OVERDOSE

A dose of more than 150 mg/kg of paracetamol is recognized as potentially hepatotoxic (unless patients are in high-risk groups) and is used as a threshold to guide therapy, such as activated charcoal, within 1 hour of ingestion. There are standard treatment guidelines to guide therapy in paracetamol overdose.[62] Chronic alcohol ingestion (> 14 units/w for women, > 21 units/w for men) has been reported to reduce the ceiling of toxicity of paracetamol, although it has not been shown definitely to potentiate the hepatotoxicity of paracetamol overdose.[63] Paradoxically, acute ingestion of ethanol reduces the toxicity of paracetamol. Adolescents with eating disorders or others with glutathione depletion may be at increased risk, as may patients who are taking enzyme-inducing drugs such as phenytoin or rifampicin, but again, this has not been definitively shown.[62]

The most common feature of untreated paracetamol overdose is hepatic injury. Other rare features include renal failure (1% in historical controls not given Nacetylcysteine) or pancreatitis.[64]In the early phase of paracetamol poisoning, it is common for the patient to remain asymptomatic, although there may be nausea and vomiting. Liver damage (with abdominal pain or tenderness) may begin to appear from 24 hours after ingestion. Renal failure occurs in only a small proportion of patients, usually those with severe liver damage and hepatic failure.[64] The key clinical action is to start the antidote (N-acetylcysteine) as early as possible because it provides complete protection against liver injury and renal failure if administered within 12 hours.[62] Patients who present 24 hours or more after ingestion of paracetamol are at higher risk of hepatotoxicity and must receive meticulous supportive care, including monitoring of acid-base status, prothrombin ratio, and creatinine. Such patients should usually receive intravenous (IV) N-acetylcysteine right away, and then their case should be discussed with a poisons center

or a liver transplant unit.[62] If hepatic damage is extensive, hepatic failure ensues on the fourth or fifth day (although it can be quicker) with encephalopathy, hypoglycemia, and coagulopathy. Sepsis may prevail and cerebral edema is a common mode of death unless successful liver transplantation takes place.

Plasma paracetamol concentration is used to guide the need for antidote (N-acetylcysteine) administration in patients presenting between 4 hours to 24 hours after an overdose. A blood sample should not be taken for plasma paracetamol estimation until 4 hours have passed since the overdose because it is not interpretable until then.[62] Occasionally, very high plasma paracetamol concentrations are seen; this can be associated with a metabolic (lactic) acidosis. The most sensitive marker of prognosis in paracetamol poisoning is the prothrombin ratio or international normalized ratio.[65] This often begins to increase within 24 hours to 36 hours of the overdose and tends to peak at 48 hours to 72 hours. Once the prothrombin ratio starts to improve, this is a sign that hepatotoxicity is starting to improve, and the patient will develop ALF.[62,65] Approximately 50% of patients who have a prothrombin time of 36 seconds at 36 hours will develop fulminant hepatic failure.[65] Plasma alanine and aspartate aminotransferases may begin to rise as early as 12 hours, but peaks do not usually occur until 72 hours to 96 hours after the overdose.[62] Aspartate or alanine aminotransferases of 12,000 IU/L are not uncommon. Hypoglycemia and metabolic acidosis are common in paracetamol poisoning.

Adverse reactions to intravenous N-acetylcysteine have been reported in as many as 5% of patients and are most likely to occur during the first hour, when the plasma concentrations are at their highest.[66] These anaphylactoid reactions include nausea, vomiting, flushing, urticaria, and pruritus. Such reactions settle on stopping the infusion for half an hour and, if necessary, giving an oral or intravenous antihistamine and

restarting at a slower rate of infusion.[62]More severe reactions include bronchospasm, angio-edema, and systemic hypotension. These require cessation of N-acetylcysteine and administration of subcutaneous or IV epinephrine.[62,66] If a patient has developed a true anaphylactic reaction to N-acetylcysteine, oral methionine can be used at a dose of 2.5 g orally every 4 hours to a total dose of 10 g. However, methionine is not as good as N-acetylcysteine in late paracetamol poisoning.

ACCIDENTAL VERSUS DELIBERATE PARACETAMOL OVERDOSES

There are a plethora of terminologies in overdose cases, and no situation shows this better than the case of intent. Less confusing terms include parasuicide (cry for help, not suicidal intent), true suicidal intent (intent to die), and therapeutic misadventure (the intent was to treat an illness but an overdose occurred, eg, children given an extra dose of pediatric paracetamol to suppress fever).[67] Unfortunately, TESS and even many poisons centers use the terms accidental or deliberate, and confusion therefore reigns in interpreting such cases. An accidental overdose is one with no overt suicidal intent and may include cases of therapeutic misadventure.

The United States reports a different pattern of overdoses from that experienced in the United Kingdom, Denmark, or Australia, where the majority of cases of paracetamol overdose are deliberate. Most U.S. overdoses are reported as unintentional. This difference may be a real phenomenon or may reflect an individual's need to claim accident to receive therapy paid for by medical insurance.

Larson *et al* (2001)[68] found that 35% of cases of ALF reported between 1998 and 2000 were attributable to paracetamol overdose. Among these cases, most (58%) were the result of an accidental overdose.[68] TESS data supports this view, suggesting 36,259

unintentional overdoses per year of paracetamol alone compared with 19,443 intentional ones.[69] In contrast, all paracetamol calls made in the United Kingdom were collected over a 14-week period (n = 280 calls).[70] Only 19 were accidental; all of these were staggered overdoses and 17 received treatment with N-acetylcysteine. Five developed hepatotoxicity; however, all alanine and aspartate transaminase and international normalized ratio (INR) abnormalities resolved within 24 hours to 48 hours. None of the patients developed acute liver failure.[70] In the United States, most cases of paracetamol overdose are unintentional and occur in children younger than 6 years (the same is true for ibuprofen). This suggests that the problem might be one of lack of awareness among parents or insecure packaging that allows children to eat tablets. This is an important point because it can be readily addressed by preventive measures.

MECHANISMS OF ACTION

NSAIDs act by reversibly or irreversibly inhibiting cyclooxygenase 1 and 2 (COX 1 and COX 2), enzymes involved in the synthesis of unstable precursors of prostaglandins. Prostaglandins play a role in a host of normal physiological processes, both in the peripheryand the central nervous system (CNS), and COX 1 is expressed constitutively in many tissues. COX 2 is induced in inflamed tissues, producing redness by dilating blood vessels, swelling by accumulation of fluid inthe extracellular spaces, and pain by sensitizing nerve endings.[58] The analgesic actions of NSAIDs are due, atleast in part, to their ability to reduce inflammation by inhibiting COX 2. However, there are additional analgesic actions, exemplified by acetaminophen, which is a good analgesic and anti-pyretic but a weak anti-inflammatory agent. These properties may be due in part to the low affinity acetaminophen has for COX in environments that are high in peroxide, such

as occurs in inflamed tissues. Acetaminophen is thought to produce analgesia both in the spinal cord and at

higher levels of the CNS. Other NSAIDs also act in the CNS to produce analgesia to varying degrees. Patients with rheumatic disease develop distinct preferences for particular agents, but whether this is due to differences in efficacy at the various sites of action is not known. ASA may also reduce the incidence of myocardial infarction and occlusive stroke by irreversible inhibition of COX 1 in platelets, which reduces their tendency to clot.

PARACETAMOL -EFFICACY IN ADULTS

The OTC dose range for paracetamol in adults is from 325 to 1000 mg every 4–6 h with a maximum daily dose of 4000 mg.[71] Despite the introduction of many new analgesics, paracetamol is still one of the most widely used analgesic–antipyretic agents. Paracetamol is a first-line choice for many clinicians for pain management and control of fever in a variety of patients, including children, pregnant women, the elderly, and those with osteoarthritis.[74]There is increasing support by clinicians for ibuprofen to replace paracetamol as a first-line treatment for fever in infants and children.[75]

Paracetamol has been shown to be effective in relieving mild to moderate pain such as headache, toothache, dysmenorrhoea, and a variety of postsurgical pain in a dose range of 650–1300 mg in a wide variety of controlled clinical trials.[71,76-78]Paracetamol has been shown to be effective in the symptomatic relief of sore throat pain and fever associated with URTI. In a double-blind placebo-controlled clinical trial on subjects with sore throat pain associated with URTI, Schachtel et al. demonstrated that a single dose of paracetamol of650 mg in 13 subjects caused a highly significant reduction in subjective

scores of sore throat pain with no reported adverse effects.[72] In a similar double-blind placebo-controlled clinical trial on subjects with sore throat pain associated with URTI, Schachtel et al. demonstrated that a single dose of 1000 mg paracetamol in 40 subjects caused a highly significant reduction in subjective scores of sore throat pain with no adverse effects.[79] In the latter trial the 1000 mg dose of paracetamol was shown to provide subjective relief from sore throat pain for up to 6 h.

Bachert et al. reported that single doses of 500and 1000 mg paracetamol were significantly better than placebo in reducing body temperature in patients with fever associated with URTI and they also reported significant relief of symptoms of headache, achiness and feverish discomfort.[73]Efficacy in children Paracetamol is especially useful for the treatment of pain and fever in infants and children, where it has a superior safety record to aspirin as regards Reye'ssyndrome.[74] Most of the clinical data regarding the efficacy of paracetamol in the treatment of fever in children has been generated from clinical trials aimed at comparing the efficacy of the newer antipyretic ibuprofen with that of the established children's antipyretic paracetamol.[80,81]In a double-blind placebo-controlled trial on children aged 2–12 years, a single dose of paracetamol 15 mg/kg was shown to be superior to placebo for treatment of sore throat pain and fever associated with URTI.[82] In a review of the first 40 years of paracetamol use in children the authors state 'paracetamol remains the first-choice OTC treatment for analgesia and antipyresis in children'.[83]

2. LITERATURE REVIEW

Brok J[84] *et al.,*(2018)

Conducted a study to assess the benefits and harms of interventions for paracetamol over dosage. Ten small and low-methodological quality randomised trials, one quasi-randomised study, and 48 observational studies were identified. It was not possible to perform relevant meta-analyses of randomised trials that have addressed their outcome measures. Activated charcoal, gastric lavage, and ipecacuanha are able to reduce the absorption of paracetamol, but the clinical benefit is unclear. Of these, activated charcoal seems to have the best risk-benefit ratio. N-acetylcysteine seems preferable to placebo/supportive treatment, dimercaprol, and cysteamine, but N-acetylcysteine's superiority to methionine is unproven. It is not clear which N-acetylcysteine treatment protocol offers the best efficacy. No strong evidence supports other interventions for paracetamol overdose. N-acetylcysteine may reduce mortality in patients with fulminant hepatic failure (Peto OR 0.26, 95% CI 0.09 to 0.94, one trial). Liver transplantation has the potential to be life saving in fulminant hepatic failure, but refinement of selection criteria for transplantation and long-term outcome reporting are required.

Shaza D[85] *et al.,*(2018)

A cross-sectional study was carried out among 400 adult patients attending the General Medicine clinic in 10 selected PHC centers in Jeddah, Saudi Arabia to estimate the prevalence and describe the pattern of OTC use among patients attending primary healthcare (PHC) centers, and to assess their knowledge and attitude regarding the related side effects. The data collected included socioeconomic parameters, practice and pattern of OTC analgesics use in past 6 months, knowledge and attitude about OTC analgesics,

and safety assessment.Results showed that 84.4% of the participants were using OTC analgesics, at least twice per week in 59.3% of the cases, and for <1 week duration in 65.8%. The prevalence of use was highest among illiterate and highly educated participants (p=0.000), and those with moderate income (p=0.011). Acetaminophen (paracetamol) was the most frequently used drug (86.1%), followed by ibuprofen (25.1%) and diclofenac (14.7%); and headache (71.1%), arthralgia (17.7%) and toothache (17.4%) were the most common conditions leading to usage. A simple health problem (64.0%), previous experience with the drug (35.1%) and lack of time (12.1%) were the most common reasons for OTC analgesics use. Among all, 58.1% admitted having no knowledge about OTC analgesic side effects; while 7.1% reported having experienced side effects. Thus concluded that there is an alarming prevalence of OTC analgesics use among patients, with inadequate levels of awareness about the associated risks. Awareness and knowledge of users should be further investigated to determine the need for information for this specific or a larger population.

Maham T[86] *et al.*,(2017)

The study assessed the prevalence of self-medication, level of awareness and knowledge regarding OTC medicines (specifically paracetamol), 352 university students through structured interview method. Awareness was scored by a ranking questionnaire. Data was coded and statistically analyzed using SPSS. The survey questionnaire covered the risk perception, prevalence of self-medication and practices regarding OTC medicine use among the university students. The results offered an indirect assessment of the knowledge among our general population as well as an estimation of misuse related harmful impact of OTC medicines. Moreover, it point out a major knowledge gap, low risk perception and significant prevalence of self-medication with paracetamol among our

population, illustrating an increased potential of its adverse effects through overuse or misuse. These finding reveal a substantial need for educational intervention around OTC medicines. Serves as an eye opener for healthcare practitioners who should be proactive in commencing health awareness programs as well as superintending the irrational OTC drug use among public.

Christina J[87] *et al.*,(2017)

This study aimed to describe the characteristics of paracetamol overdose in the adult population managed at a tertiary healthcare facility in Singapore. total of 177 patients had paracetamol overdose. The median age was 25 years, with a significant female predominance (71.2%). Intentional ingestion accounted for the majority (76.8%) of cases. The median dose of paracetamol ingested was 10 (interquartile range 8–15) g. Among patients who reported ingesting more than 10 g, 46.5% perceived the overdose as non-lethal. N-acetylcysteine was administered in 76.3% of patients, among whom 24.4% experienced an anaphylactoid reaction. Of the 10 (5.6%) patients who had severe hepatotoxicity, 2 (1.1%) developed acute liver failure. Most patients had resolving transaminases at discharge and none required liver transplantation. The median length of hospitalisation was three days. There were no fatalities. They concluded the study stating that Paracetamol overdose occurred predominantly in young adults with intentional ingestion, suggesting that preventive measures targeted at promoting public awareness may not suffice. However, the perceived lack of lethality by many patients who ingested potentially toxic amounts of paracetamol reflects a certain knowledge gap. Healthcare providers should proactively educate consumers on the proper use of paracetamol and the consequences of its overdose.

Dibya S[88]*et al.*, (2017)

A descriptive cross sectional was conducted from 1st February - 15th August 2016 among 110 among adults of age group 20 and above residing in Chapapani-12, Pokhara. A pre-tested structured questionnaire were used and data were analyzed using Statistical Package for Social Science (SPSS) for windows version 18.0. Frequency, percentage, chi-square and correlation were performed. Nearly 1/3rd of the respondents (33.6%) were of age group 20-29 years and more than half (60.9%) were female. More than half of the respondents (54%) had good knowledge and less than half (47%) had good practice of OTC. There was significant association of knowledge with age, marital status, education and monthly family income. There was significant association of practice with education of respondents. There was weak positive correlation between knowledge and practice (r =0.211). This study showed that the knowledge hadn't been fully practiced into action by the community people and still they are lacking the concept of over-the-counter drugs and its safe use in daily living.

Nahla K[89]*et al.*,(2015)

They conducted a cross sectional study to determine the prevalence and predictors of self-medication with analgesics among senior medical students and interns in King Abdulaziz University (KAU), Jeddah, Saudi Arabia. A multistage stratified random sampling was used. A confidential, anonymous & self-administered questionnaire was used to collect personal & socio-demographic data. Data about self-medication and self-medication with analgesics during the preceding 6 months were also inquired from 504 participants. Both descriptive and analytical statistics were done by SPSS version 18 &Epi-Info. During the 6 months preceding the study, 75.2% and 55.4% of participants used self -medication & analgesic self-medication, respectively. The first predictor of utilization of analgesic self-

medication was living with family (aOR; 1.96, 95% CI: 1.22-3.14), followed by age >21 years & non- professional jobs of fathers. Therefore they noted that alarming high rates of self medication and self-medication with analgesics were observed among medical students and interns. Self-medication needs improvement through educational, regulatory and managerial strategies.

Giselle S[90] et al., (2015)

This study describes the prevalence, trends, associations and patterns of use of prescription and over-the-counter (OTC) analgesics, focusing on five of the most common agents: aspirin, diclofenac, ibuprofen, naproxen and paracetamol. The result showed that analgesic use has increased over the last decade from 19 to 21 %. This was exclusively due to the rise in OTC analgesic use from 10.0 to 12.2 %. Prescribed analgesic use remained constant (7.9 %). Findings indicate that ibuprofen is the most commonly used analgesic followed by aspirin and paracetamol. OTC analgesic use is higher among women and smokers, but lower among older adults (65–79 years). Prescribed analgesics use is higher among women, older adults, smokers and obese adults with medium or high socio- economic status. Adults performing more than 2 h/week of physical exercise use fewer analgesics. Hence they concluded the study stating about one in five community dwelling adults aged 18–79 years in Germany use analgesics in a given week. Considering the potential harms of analgesic use, monitoring of prevalence, patterns and determinants of use at the population level are important steps to inform disease prevention and health promotion policies

Varun K[91] et al., (2015)

A cross-sectional study was designed to study the prevalence and practice of self-medication practices in an urban area of Delhi, India. Datas were collected by personal interviews using pretested questionnaires. An urban colony in the south district of Delhi was chosen and the eldest member of the family, present at the time of the visit was interviewed. Data were collected from 236 persons and analyzed using SPSS version 21. The prevalence of self-medication was 92.8% (95 confidence interval: 66.5-79.4). 74.9% preferred allopathic medicines. Self-medication was found to be practiced more among younger persons than older age group persons (P =0.000). Graduates and postgraduates practiced self-medication more than others (P = 0.002). Common cold (61.6%) and fever (51.8%) were the most common ailments for which self-medication were practiced. Paracetamol and cough syrups were the most commonly used class of drugs. Thus, The prevalence of self-medication in this study was high. Drugs especially antimicrobials were not taken for the proper length of time. Awareness regarding self-medication practices to help patients decide on the appropriateness of self-medication was considered to be required in this study.

Roderick C[92] et al., (2012)

They conducted an observational study to find out the population prevalence of high dose paracetamol in dispensed paracetamol/opioid prescription combinations. The Nova Scotia Prescription Monitoring Program (NSPMP) in the Canadian province of Nova Scotia is a legislated organization that collects dispensing information on all out-of-hospital prescription controlled drugs dispensed for all Nova Scotia residents. The NSPMP provided data to track all paracetamol/opioids redeemed by adults in Nova Scotia, from July 1, 2005 to June 30, 2010. Trends in the number of adults dispensed these

prescriptions and the numbers of prescriptions and tablets dispensed over this period were determined. The numbers and proportions of adults who filled prescriptions exceeding 4.0 g/day and 3.25 g/day were determined for the one-year period July 1, 2009 to June 30, 2010. Data were stratified by sex and age (<65 versus 65+).Both the number of prescriptions filled and the number of tablets dispensed increased over the study period, although the proportion of the adult population who filled at least one paracetamol/opioid prescription was lower in each successive one-year period. From July 2009 to June 2010, one in 12 adults (n = 59,197) filled prescriptions for over 13 million paracetamol/opioid tablets. Six percent (n = 3,786) filled prescriptions that exceeded 4.0 g/day and 18.6% (n = 11,008) exceeded 3.25 g/day of paracetamol at least once. These findings exclude non-prescription paracetamol and paracetamol–only prescribed medications. Thus, a substantial number of individuals who redeem prescriptions for paracetamol/opioid combinations may be at risk of paracetamol-related hepatotoxicity. Healthcare professionals must be vigilant when prescribing and dispensing these medications in order to reduce the associated risks.

Laura P[93] et al., (2011)

The objectives were to assess: adolescents': 1) health literacy; 2) knowledge about acetaminophen; 3) recent use of over-the-counter (OTC) medicines; 4) and use of medication dosing instructions to understand the medicine and how to use it. It was a cross-sectional survey of adolescents and young adults (ages 16–23 years) recruited from education settings and health care sites in Monroe County, New York, from 11/08–9/09. Using structured in-person interviews, assessement of acetaminophen knowledge, recent use of over-the-counter (OTC) medicines was performed. Confusion about acetaminophen and its use was common. Limited health literacy was an independent risk

factor for poor knowledge, misunderstanding, and potential unsafe use of acetaminophen-containing medicines, however, most participants at all health literacy levels erred dangerously in 'unsafe' understanding of acetaminophen use from label instructions.

Alemayehu A[94] *etal.*, (2011)

This study was conducted to find out the Frequent Use of Paracetamol and Risk of Allergic Disease Among Women in an Ethiopian Population. In 2005/6 a population based cohort of 1065 pregnant women was established in Butajira, Ethiopia and baseline demographic data collected. At 3 years post birth, an interview-based questionnaire administered to 945 (94%) of these women collected data on asthma, eczema, and hay fever in the past 12 month, frequency of paracetamol use and potential confounders. Allergen skin tests to Dermatophagoidespteronyssinus and cockroach were also performed. The independent effects of paracetamol use on allergic outcomes were determined using multiple logistic regression analysis. The prevalence of asthma, eczema and hay fever was 1.7%, 0.9% and 3.8% respectively; of any one of these conditions 5.5%, and of allergen sensitization 7.8%. Paracetamol use in the past month was reported by 29%, and associations of borderline significance were seen for eczema (adjusted OR (95% CI) = 8.51 (1.68 to 43.19) for 1–3 tablets and 2.19 (0.36 to 13.38) for $4 tablets, compared to no tablets in the past month; overall p = 0.055) and for 'any allergic condition' (adjusted OR (95% CI) = 2.73 (1.22 to 6.11) for 1–3 tablets and 1.35 (0.67 to 2.70) for $4 tablets compared to 0 in the past month; overall p = 0.071).Thus this study provides further cross-sectional evidence that paracetamol use increases the risk of allergic disease.

Daniel S[95]*et al.*, (2011)

A study was conducted to estimate the frequency of and characterize risks for emergency department visits for acetaminophen overdoses that were not related to abuse in the U.S. The result showed that there were an estimated 78,414 emergency department visits (95% CI63655, 93172) annually for non-abuse-related overdoses of acetaminophen-containing products. Most emergency department visits for acetaminophen overdose were for self-directed violence (69.8%, 95% CI66.4%, 73.2%), with the highest rate among patients aged 15–24 years (46.4 per 100,000 individuals per year). Unsupervised ingestions by children aged 6 years accounted for 13.4% (95% CI11.0%, 15.9%) of visits for acetaminophen overdoses (42.5 per 100,000 individuals per year). Therapeutic misadventures accounted for 16.7% (95% CI14.0%, 19.5%) of visits and most involved overuse for medicinal effects (56.1%, 95% CI50.6%, 61.6%) rather than use of multiple acetaminophen-containing products or dose confusion. Hence, Non-abuse-related overdoses of acetaminophen products lead to many emergency department visits each year, particularly emergency department visits for self-directed violence. Acetaminophen overdose prevention efforts will likely need to be multidimensional.

3. AIM AND OBJECTIVES

Acetaminophen is the most commonly used medication It can be used in both adult and pediatric populations and can be an effective analgesic and antipyretic to relieve symptoms associated with injury, viral and bacterial infections, and headaches.[96-98]Although considered safe when taken as recommended, liver toxicity can occur with doses greater than 4 g or when used in patients with preexisting liver dysfunction.[96,99] Acetaminophen toxicity is the most common cause of acute liver failure and is the most common reason for calls made to poison control centers.[97,100] It has been estimated that overdose with acetaminophen leads to more than 56,000 emergency department visits, more than 2,600 hospitalizations, and approximately 400 deaths from acute liver failure every year. Acetaminophen is available in multiple dosage forms, including oral pills and liquids, suppositories, and even intravenous formulations in some hospitals. Because of its presence in so many different products, patients may not recognize which products contain acetaminophen. An estimated 15% of acute liver failure cases result from patients who unknowingly consumed multiple acetaminophen-containing preparations simultaneously and more than 100 deaths annually are caused by unintentional overdose.[97,98]

Food and Drug Administration (FDA) issued several recommendations for labeling of OTC pain relievers. In 2006, FDA proposed adding a new warning for liver damage and making the active ingredient more prominent on the packaging.[100] These changes were finalized in 2009 with some additional requirements.[101] The new regulations require the liver warning to be present on the immediate container and the outer carton labeling. In addition, a warning appears stating that patients should not use acetaminophen with warfarin and that they should ask a physician or pharmacist if they are unsure whether a

medication contains acetaminophen. Examining the effect of these changes on patient knowledge of acetaminophen safety, dosing, and identification is important.

Better identification of gaps in patient knowledge regarding the presence of acetaminophen in OTC medications is needed. This will facilitate development of interventions to increase patient safety, prevent overdoses, and guide patients in obtaining appropriate care following an overdose.

Aim

To evaluate patient knowledge of over-the-counter (OTC) products containing acetaminophen.

Objectives

To study the patient knowledge and ability of safe use OTC products containing acetaminophen, including understanding risks, identifying products, and dosing different formulations.

4. METHODOLOGY

The purpose of this study was to evaluate public knowledge about OTC acetaminophen-containing products. This study will involve administration of a cross-sectional interview to a calculated sample of participants (377) at pharmacies. The sites included two community pharmacy shops located in Kumarapalayam, Tamilnadu. The interviewers set up a booth inside participating community pharmacies and invited patrons to participate in a 10 to 15minutes survey. Participants received acetaminophen educational materials upon completion of the interview. All the participants had knowledge of identifying OTC products containing acetaminophen. Patients were invited to participate if they were at least18 years of age. Participants who did not have professional training to handle medications (e.g., physician, nurse, pharmacist) was also eligible to participate. The populations were all users of medication or caregivers who resorted to pharmacies to pickup acetaminophen alone or along with other medications, without prescriptions. Patients were excluded from the study if they were pregnant, under the age of 18 years, no knowledge of identifying OTC products containing acetaminophen, unable to communicate due to being illiterate or deaf, unable to be transported to and from the pharmacy, or mentally ill, health sciences students, and unable to provide accurate answers. Identified patients were contacted by the investigator about participating in the study. Participation was voluntary, and all patients gave informed consent.

A questionnaire was developed based on literature, which includes items to evaluate patient knowledge and use of acetaminophen, education received about acetaminophen, daily alcohol consumption, and location of pharmacy services. The questionnaire was approved by Institutional Review Board. A standardised questionnaire was utilized to collect all data. The Participants was allowed to respond to this question in whatever way

they could, without prompting to answer in any specific manner (that is, g/day, mg/day, pills/day). Answers were recorded in multiple formats according to patient responses, including: mg/day, g/day, number of pills of specific dose/day. These responses were converted into a maximum daily dose in mg. Patients were then asked if they had ever taken more than the recommended maximum daily dose of acetaminophen, and if so, their reason for doing so.

Analysis

The data was captured and analysed using SPSS21. The relevant themes were documented based on the literature. Answers from questions determining the participants understanding of each form of information were either classified as correct or incorrect to determine their level of information comprehension. Descriptive statistics were used to determine the frequency of variables.

5. RESULTS

Table 1. Gender distribution among the participants

S.No	Gender	Number of Patients	Percentage (%)
1	Male	253	67.11
2	Female	124	32.89

Figure 1. Gender distribution among the participants

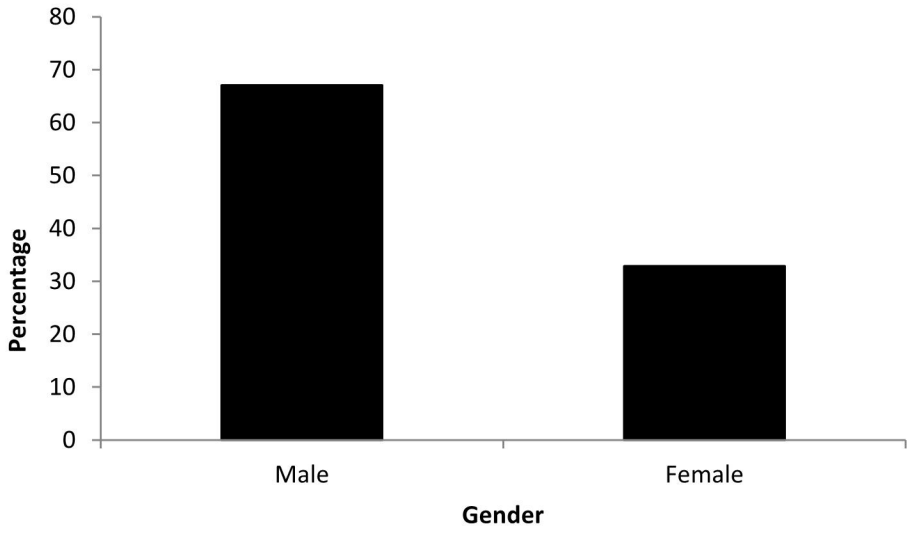


Table 2.Age Distribution among the participants

S.No	Age (years)	Number of Patients	Percentage (%)
1	< 20	54	14.32
2	21-40	90	23.87
3	41-65	151	40.05
4	> 65	82	21.75

Figure 2. Age Distribution among the participants

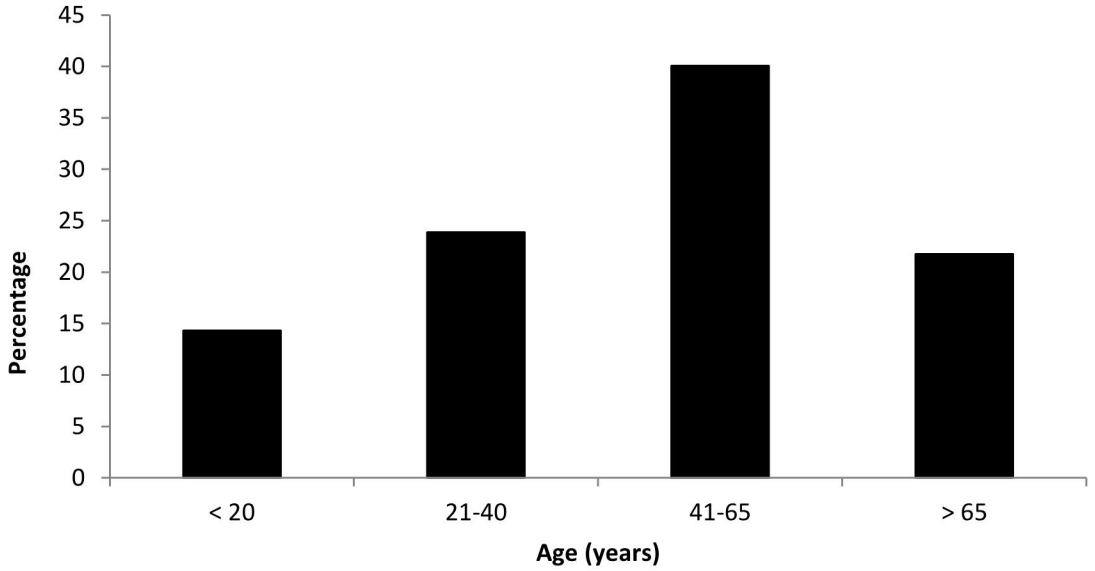


Table 3.Educational Status Distribution among the participants

S.No	Education	Number of Patients	Percentage (%)
1	Illiterate	46	12.2
2	High school level	175	46.42
3	College level	156	41.38

Figure 3. Educational Status Distribution among the participants

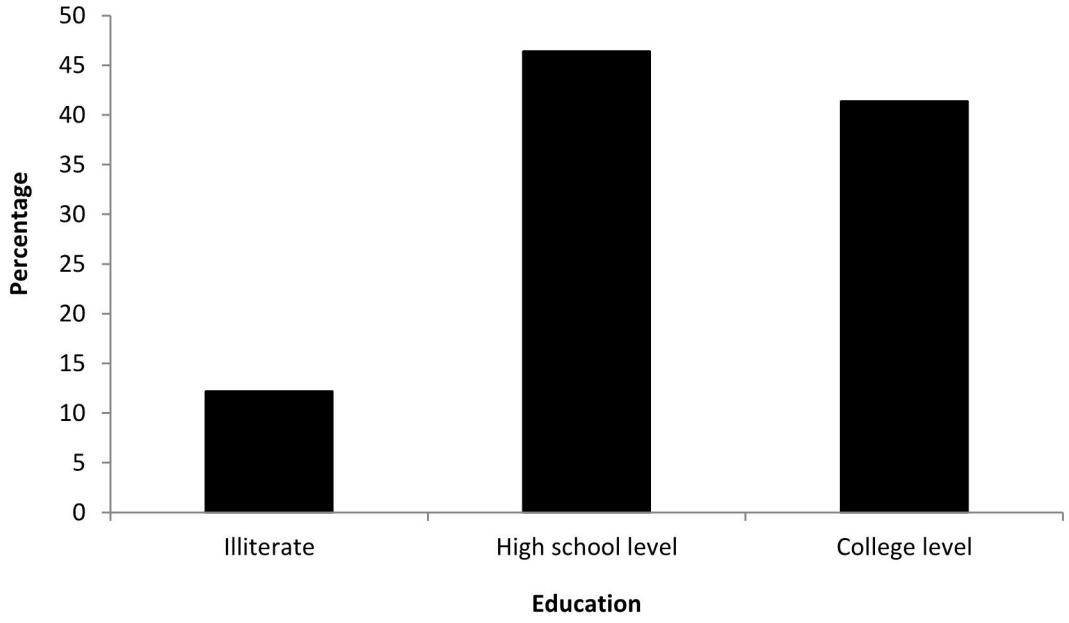


Table 4.Monthly income distribution among the participants

S.No	Monthly income	Number of Patients	Percentage (%)
1	Lower	121	32.10
2	Upper lower	204	54.11
3	Lower middle	47	12.47
4	Upper middle	5	1.33

Figure 4. Monthly income distribution among the participants

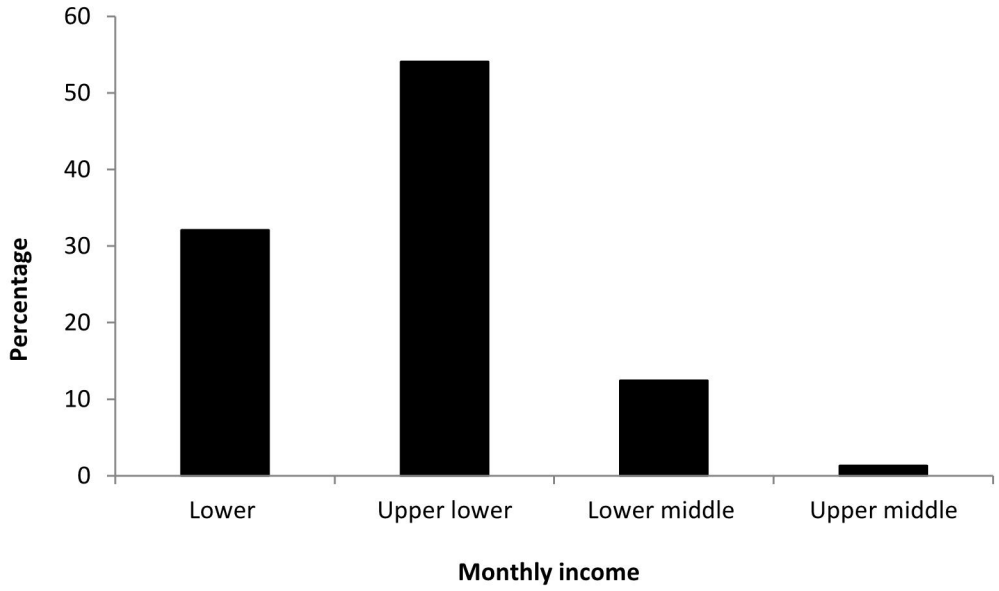


Table 5.Reasons for use of Paracetamol among the participants

S.No	Reasons for use of Paracetamol	Number of Patients	Percentage (%)
1	Headache	159	42.18
2	Fever	88	23.34
3	Cold and flu	57	15.12
4	Arthralgia	73	19.36

Figure 5. Reasons for use of Paracetamol among the participants

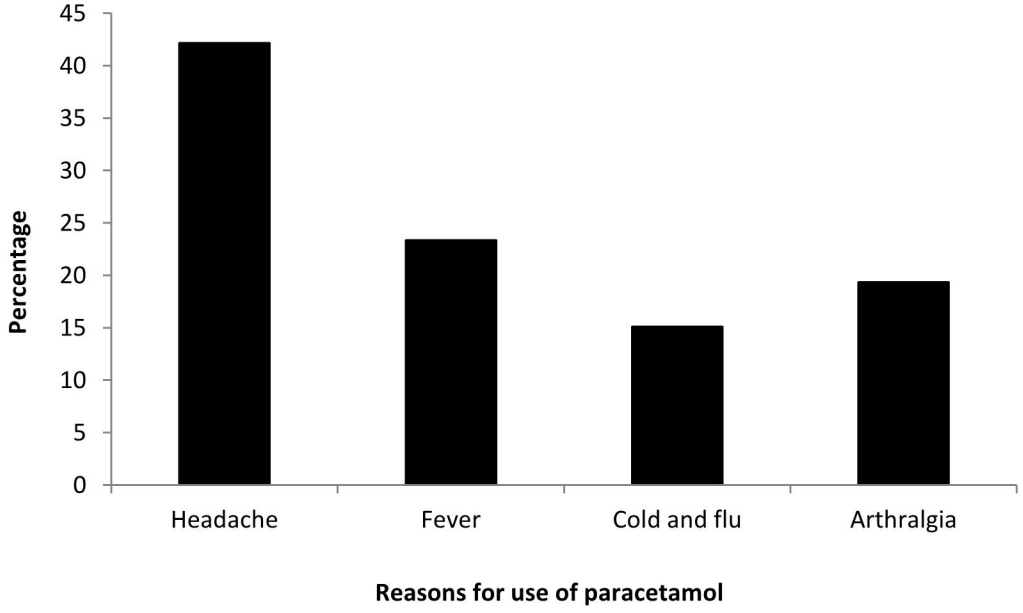


Table 6. Dosage form purchased among the participants

S.No	Dosage form purchased	Number of Patients	Percentage (%)
1	Liquid orals	86	22.81
2	Tablets	291	77.19

Figure 6. Dosage form purchased among the participants

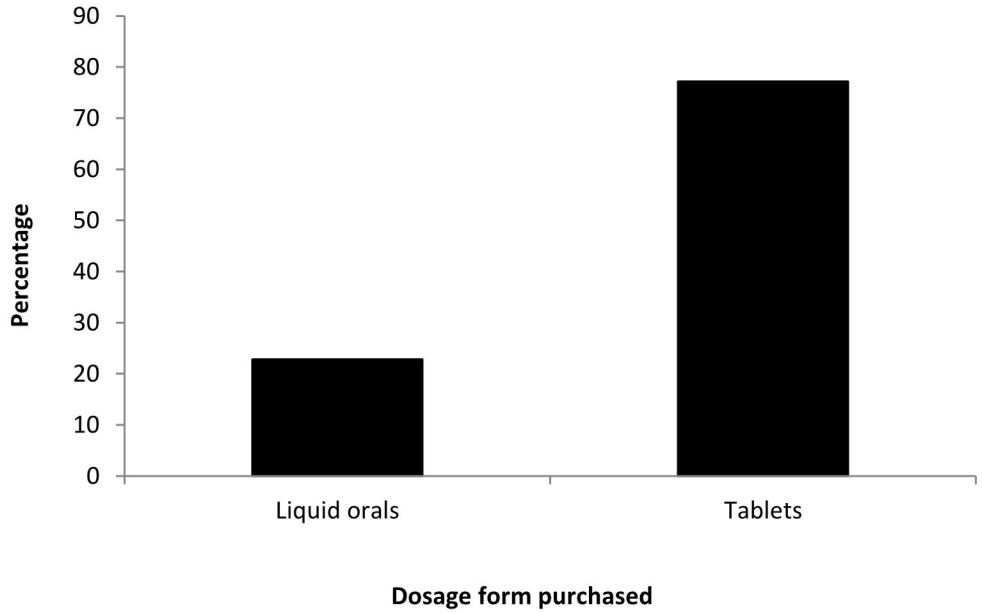


Table 7. Knowledge about Strength of tablets among the participants

S.No	Knowledge about Strength of tablets	Number of Patients	Percentage (%)
1	Yes	301	79.84
2	No	76	20.16

Figure 7. Knowledge about Strength of tablets among the participants

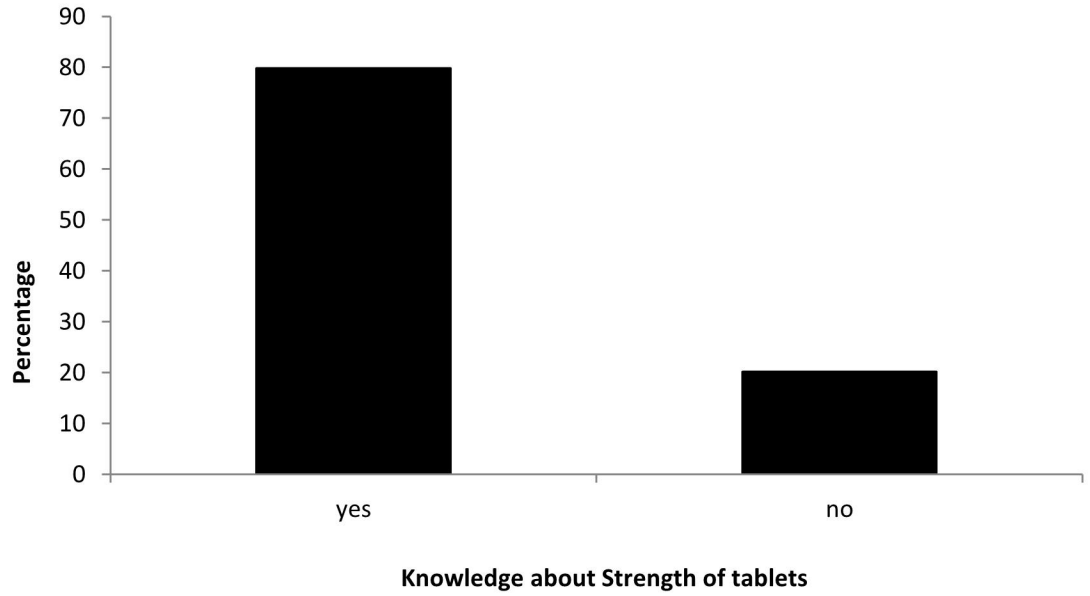


Table 8: Knowledge about Strength of tablets - if answer is yes-, Knowledge about strengths available in market

S.No	Knowledge about strengths available in market	Number of Patients	Percentage
1	100 mg	65	17.24
2	250 mg	23	6.10
3	325 mg	12	3.18
4	500 mg	179	47.48
5	650 mg	149	39.52

Figure8: Knowledge about Strength of tablets - if answer is yes- , Knowledge about strengths available in market

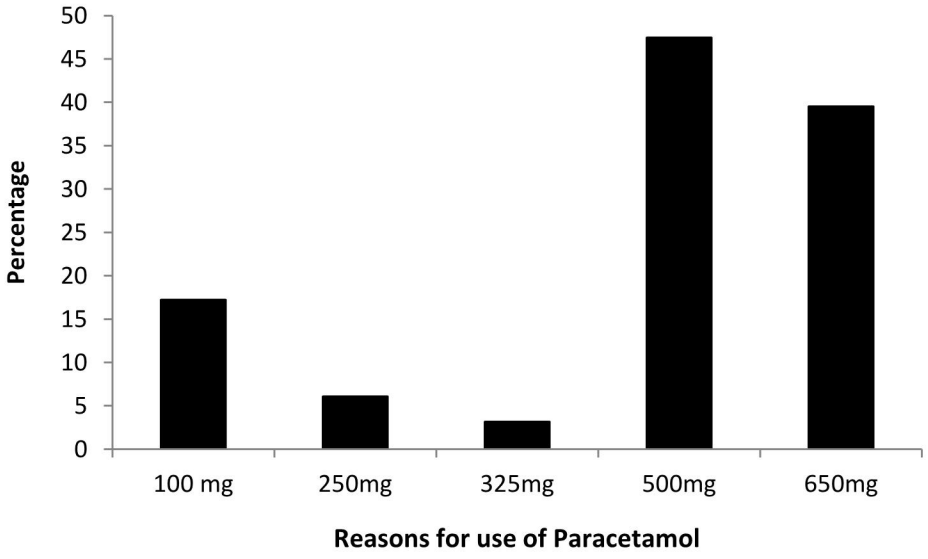


Table 9: Knowledge about Liquid Orals

S.No	Knowledge about Liquid Orals	Number of Patients	Percentage (%)
1	No	237	62.86
2	Yes	140	37.13

Figure 9: Knowledge about Liquid Orals

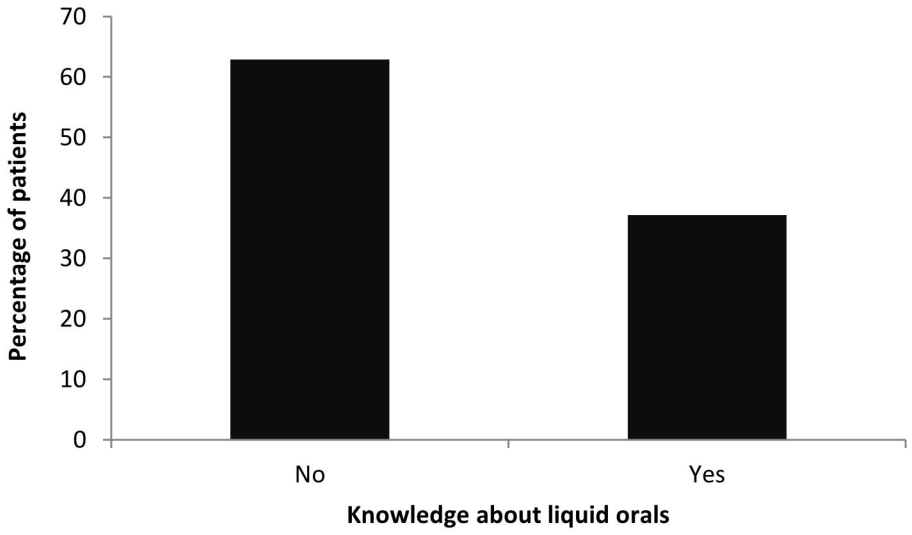


Table 10: Knowledge about Liquid Orals - if answer is yes- Knowledge about strengths of Liquid Orals available in market

S.No	Knowledge about strengths of Liquid Orals available in market	Number of Patients	Percentage (%)
1	120 mg/5 ml	21	5.57
2	250 mg/5 ml	57	15.12
3	500 mg/5 ml	62	16.45

Figure 10: Knowledge about Liquid Orals - if answer is yes- , Knowledge about strengths of Liquid Orals available in market

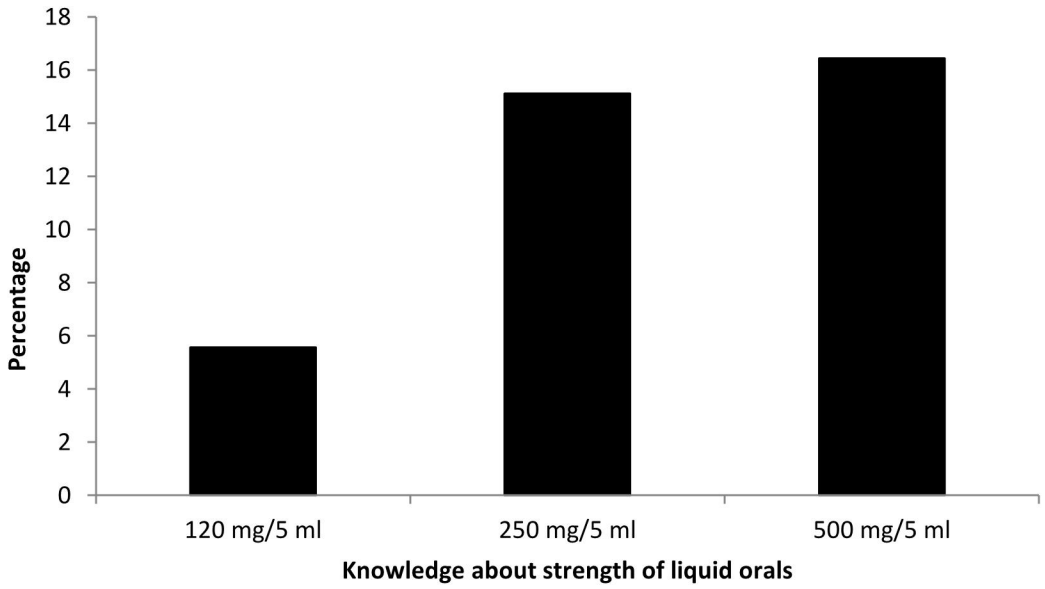


Table 11:Knowledge about Number of doses of paracetamol that can be taken per day

S.No	Knowledge about Number of doses/day	Number of Patients	Percentage (%)
1	1	74	19.63
2	2	101	26.79
3	3	38	10.08
4	4	27	7.16
5	don't know	137	36.34

Figure 11:Knowledge about Number of doses of paracetamol that can be taken per day

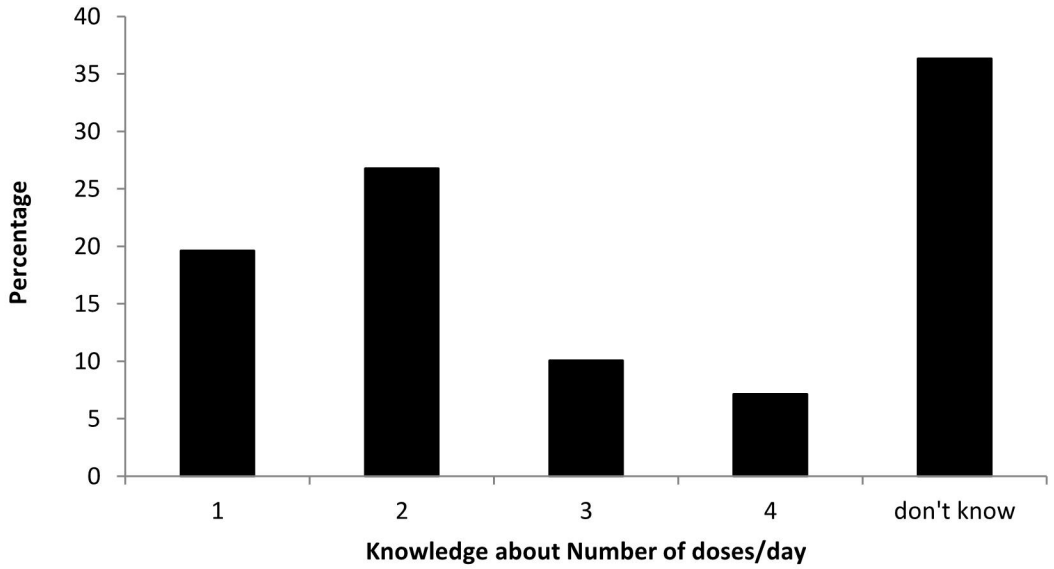


Table 12:Knowledge about Minimum time between doses

S.No	Minimum time between doses	Number of Patients	Percentage (%)
1	Correct	72	19.1
2	Don't know	227	60.21
3	Inappropriate	78	20.69

Figure 12: Knowledge about Minimum time between doses

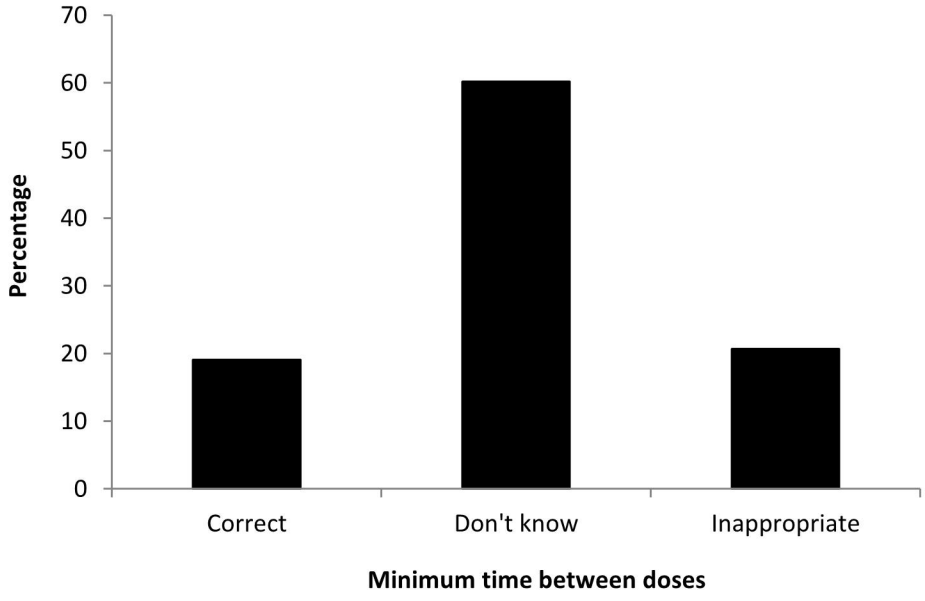


Table 13:Knowledge about Maximum single dose

S.No	Maximum single dose	Number of Patients	Percentage (%)
1	0.5 g	116	30.77
2	0.65 g	127	33.69
3	1 g	71	18.83
4	2	5	1.33
5	2 g	0	0.00
6	4 g	0	0.00
7	Don't know	58	15.38

Figure 13:Knowledge about Maximum single dose

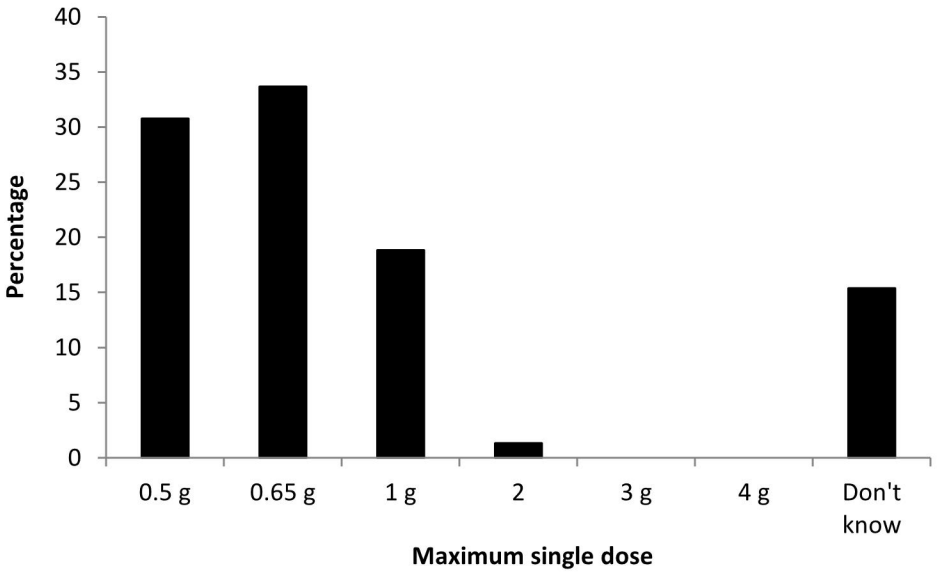


Table 14:Knowledge about Maximum daily dose of paracetamol

S.No	Maximum daily doses of paracetamol	Number of Patients	Percentage (%)
1	0.5 g	47	12.47
2	1 g	98	25.99
3	2g	99	26.26
4	3 g	0	0
5	4 g	0	0
6	5 g	0	0
7	Don't know	133	35.28

Figure 14:Knowledge about Maximum daily dose of paracetamol

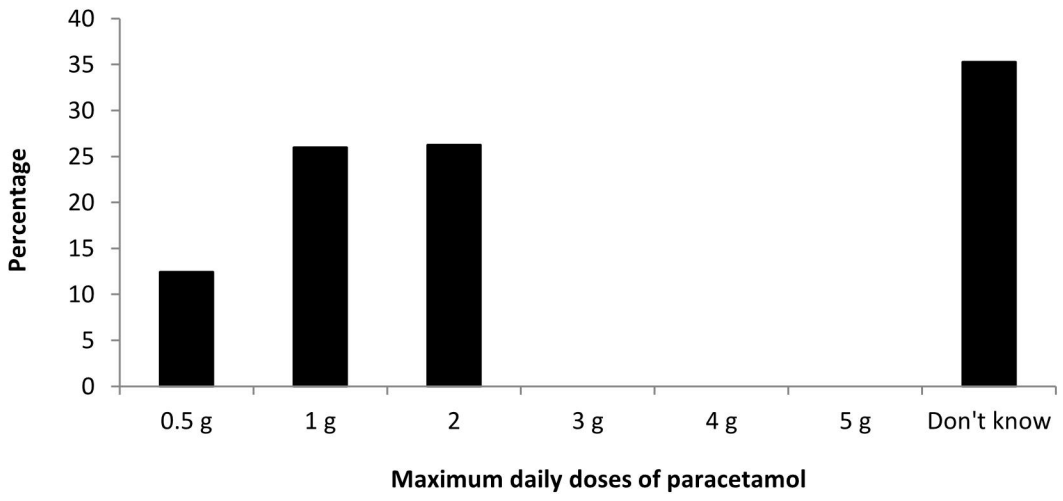


Table 15:Knowledge about excessive use of paracetamol

S.No	Can it be harmful to consume too much paracetamol	Number of Patients	Percentage (%)
1	Yes	237	62.86
2	No	106	28.12
3	Don't know	34	9.02

Figure 15: Knowledge about excessive use of paracetamol

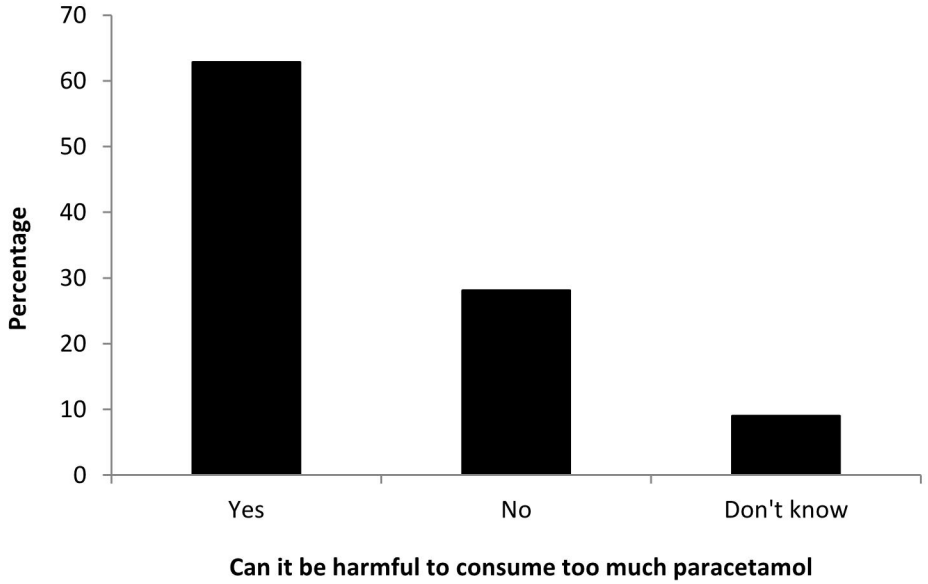


Table 16: Can it be harmful to consume too much paracetamol --- if answer is yes -- What types of effects may cause this drug?

S.No	Types of effects may cause this paracetamol?	Number of Patients	Percentage (%)
1	Deat3h	132	35.01
1	Liver problems	76	20.16
2	Other problems	39	10.34
3	Don't know	56	14.85

Figure 16: Can it be harmful to consume too much paracetamol --- if answer is yes -- What types of effects may cause this drug?

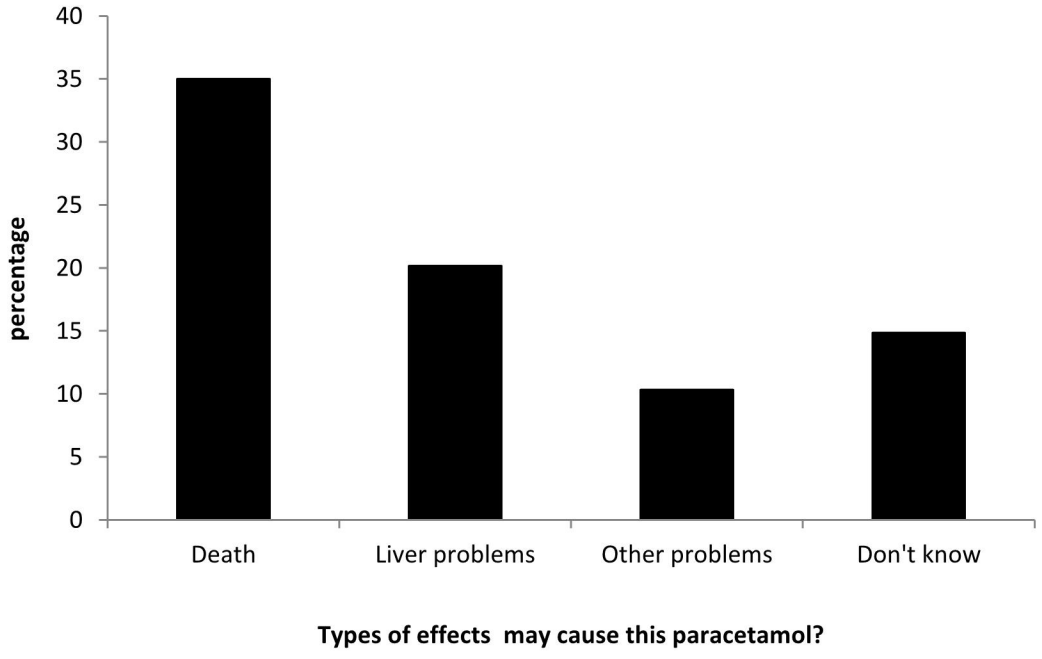


Table 17: Knowledge about Drug interactions with Paracetamol

S.No	Can it be harmful to take Paracetamol with other medications?	Number of Patients	Percentage (%)
1	Yes	310	82.23
2	No	46	12.2
3	Don't know	21	5.57

Figure 17: Knowledge about Drug interactions with Paracetamol

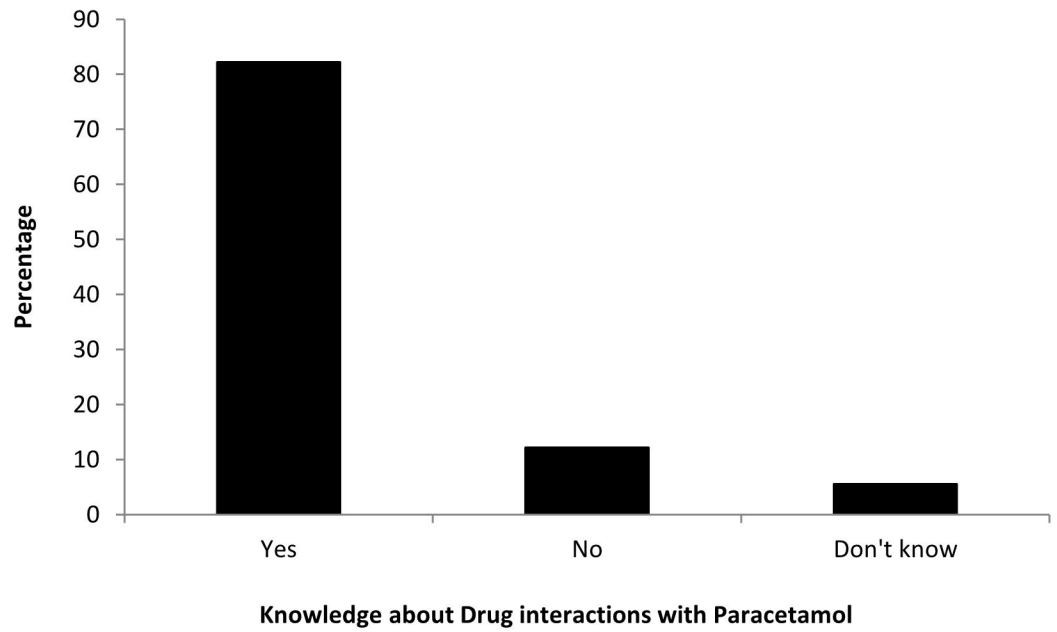


Table 18: Knowledge about use of Paracetamol during pregnancy

S.No	Knowledge about acetaminophen during pregnancy	Number of Patients	Percentage (%)
1	Yes	198	52.52
2	No	179	47.48

Figure 18: Knowledge about use of Paracetamol during pregnancy

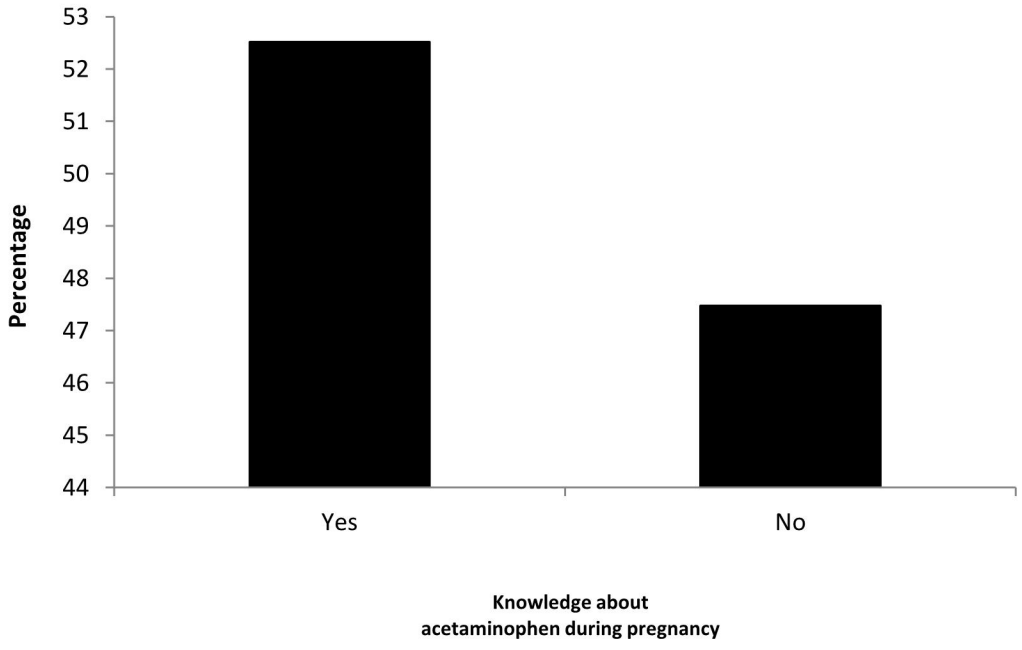


Table 19: Recommendation of paracetamol as OTC

S.No	Recommendation of paracetamol as OTC	Number of Patients	Percentage (%)
1	Family	38	10.08
2	Friends	235	62.33
3	Advertisement (Excluding Internet)	55	14.59
4	Doctors only	31	8.22
5	Internet	18	4.77

Figure 19: Recommendation of paracetamol as OTC

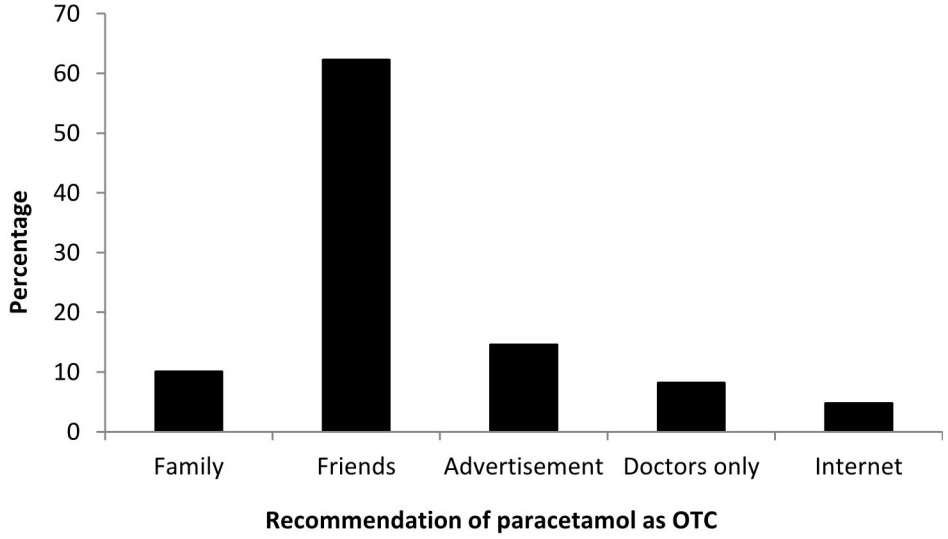


Table 20: Advised someone to use paracetamol

S.No	Advised someone to use paracetamol	Number of Patients	Percentage (%)
1	Yes	287	76.13
2	No	90	23.87

Figure 20: Advised someone to use paracetamol

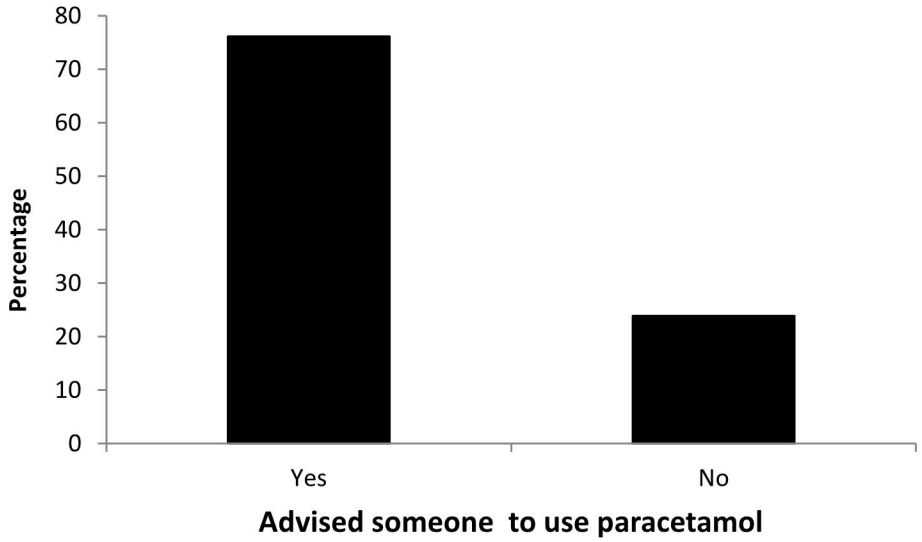


Table 21: Do you think self-prescribing is harmful?

S.No	Do you think self-prescribing is harmful	Number of Patients	Percentage (%)
1	Yes	211	55.97
2	No	166	44.03

Figure 21: Do you think self-prescribing is harmful?

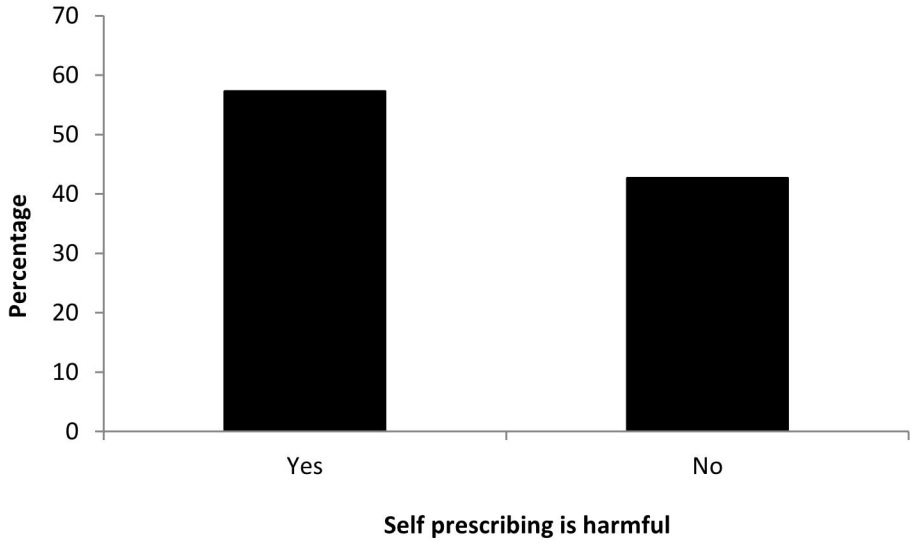


Table 22: Reason for purchasing of medication

S.No	Purchasing medication	Number of Patients	Percentage (%)
1	For Own use	168	44.56
2	For Care giver (for Adult)	112	29.70
3	For Care giver (For Children)	97	25.72

Figure 22: Reason for purchasing of medication

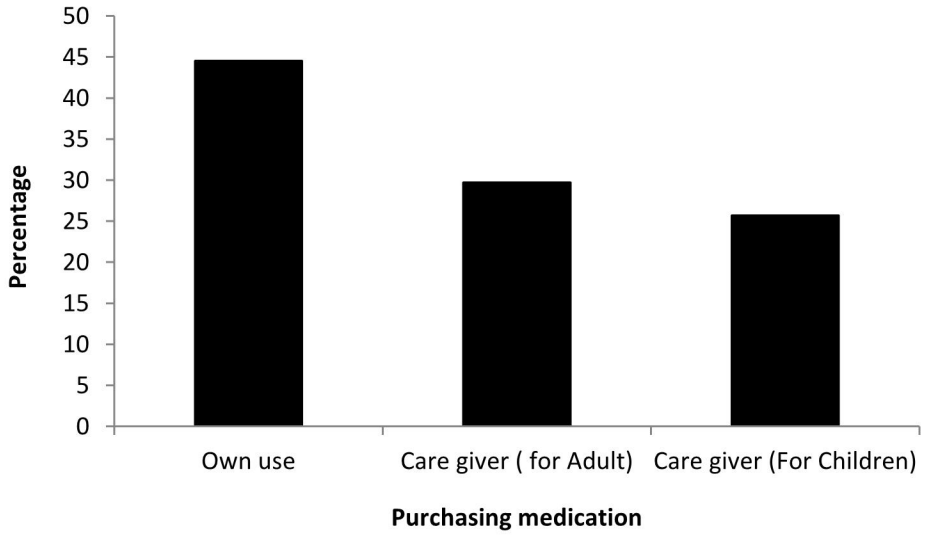


Table 23: Knowledge assessment – Is it safe to give this medication to a child under the age of 6 years?

S.No	Is it safe to give this medication to a child under the age of 6 years?	Number of Patients	Percentage (%)
1	Yes	223	59.15
2	No	154	40.85

Figure 23: Knowledge assessment – Is it safe to give this medication to a child under the age of 6 years?

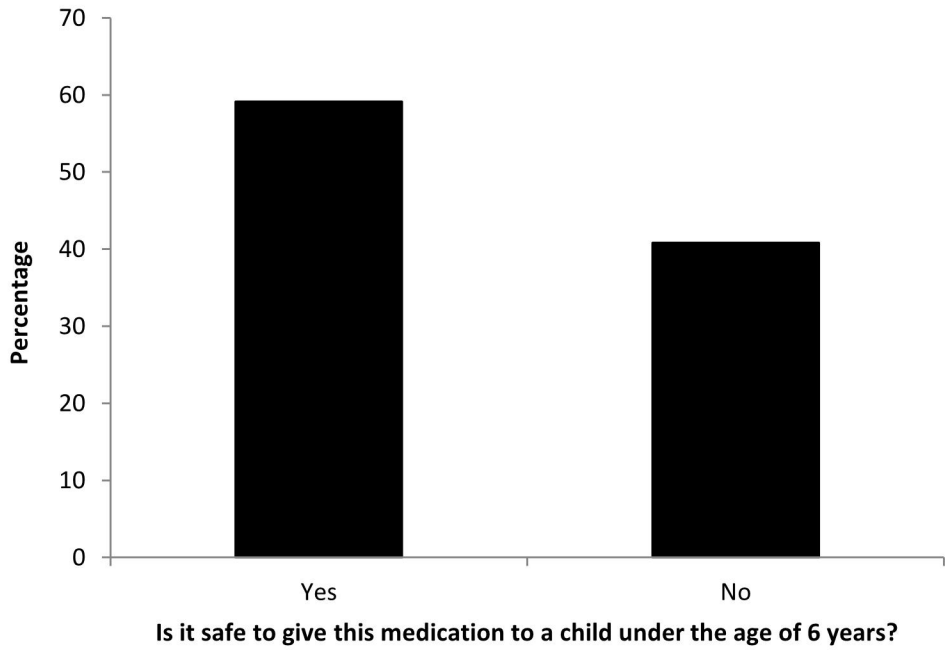


Table 24: Knowledge on the measuring devices used for administrating syrups-- Measuring devices used for administrating syrups?

S.No	Knowledge on the measuring devices used for administrating syrups-- Measuring devices used for administrating syrups?	Number of Patients	Percentage (%)
1.	Standard cup	147	38.99
2.	Spoon	41	10.88
3.	Dropper	152	40.32
4.	Other	37	9.81

Figure 24: Knowledge on the measuring devices used for administrating syrups-- Measuring devices used for administrating syrups?

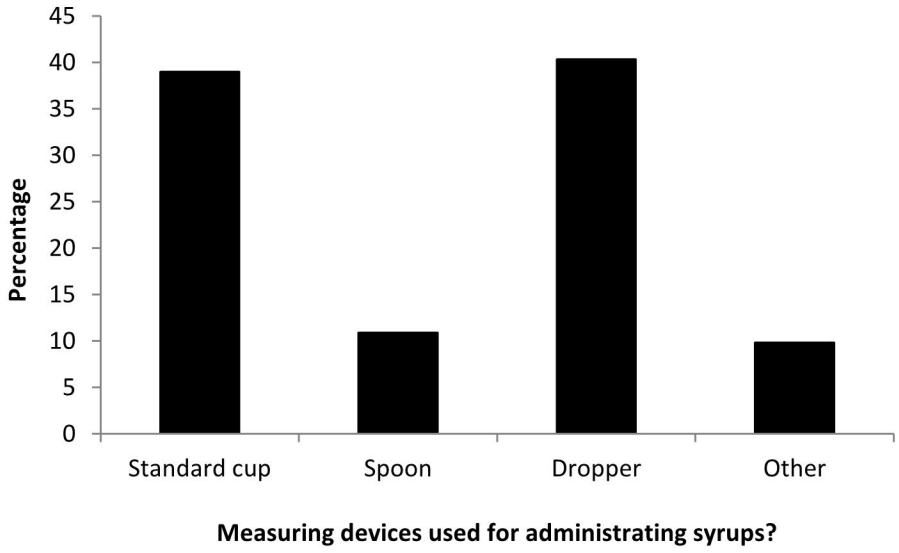


Table 25: Assessing the prevalence of participants who check the expiry date of the medication

S.No	Do you check expiry Date	Number of Patients	Percentage (%)
1	Yes	217	57.56
2	No	160	42.44

Figure 25: Assessing the prevalence of participants who check the expiry date of the medication

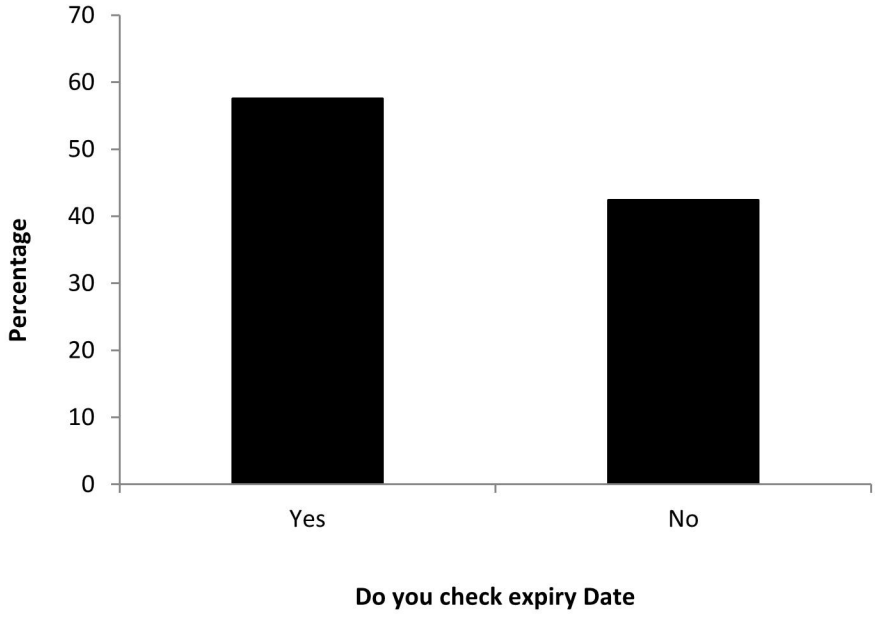


Table 26: Assessing the prevalence of participants who use leftover medications

S.No	Do you use leftover medications	Number of Patients	Percentage (%)
1	Yes	227	60.21
2	No	150	39.79

Figure 26: Assessing the prevalence of participants who use leftover medications

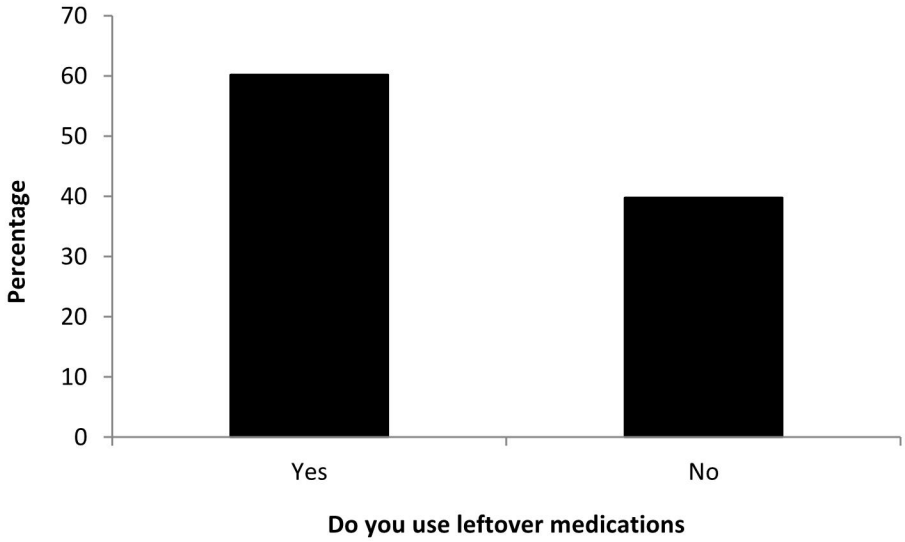


Table 27: If you purchase medicine containing Paracetamol your pharmacist asks you what other medications you are taking.

S.No	If you purchase medicine containing Paracetamol your pharmacist asks you what other medications you are taking	Number of Patients	Percentage (%)
1	Maximum daily dose	102	27.06
2	For use with / after meals	212	56.23
3	To drinking sufficient amount of water	3	0.80
4	About drugs which should not be combined with Paracetamol	2	0.53
5	about the cost of medication	1	0.27
6	About nothing	77	20.42

Figure 27: If you purchase medicine containing Paracetamol your pharmacist asks you what other medications you are taking.

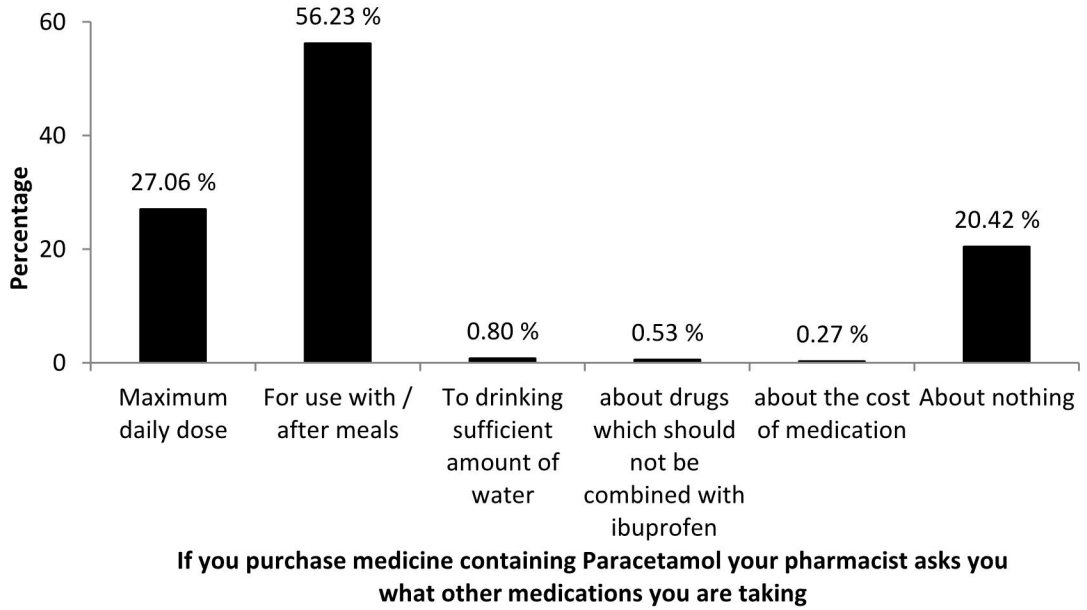
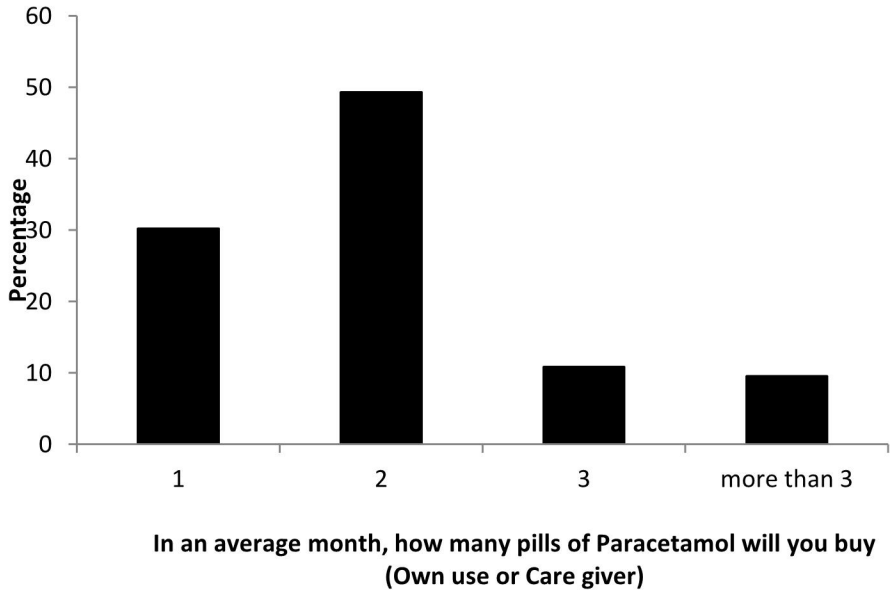


Table 28: Assessing how many pills of paracetamol is been purchased in a average month

S.No	In an average month, how many pills of Paracetamol will you buy (Own use or Care giver)	Number of Patients	Percentage (%)
1	1	114	30.24
2	2	186	49.34
3	3	41	10.88
4	more than 3	36	9.55

Figure 28: Assessing how many pills of paracetamol is been purchased in a average month



6. DISCUSSION

The decision to use any analgesic is a balance of benefit and risk. In the case of analgesics, it is important to balance the therapeutic benefit against both the risk in therapeutic use and the risk (and ease of treatment) in overdose. Paracetamol in therapeutic dose carries little risk of adverse events. Less than 0.1% of the estimated 30 million paracetamol users in the United Kingdom attend hospital with a paracetamol overdose each year, and approximately 200 people die, most of whom presented late or did not receive the antidote, N-acetylcysteine, within 12 hours but the scenario in developing countries including India is three times more than in UK since poverty and lack of education is still a major challenge.[102]

In this study a total of 377 participants was include, out of which 253 (67.11%) are male and 124 (32.89%) are female (Table 1,Figure 1). When the age distribution was considered 151 participants came under the age group of 41-65 years, 90 participants came under the age group of 21-40 years, 82 participants came under the age group of >65 years and 54 participants came under the age group of <20 years.(Table 2, Figure2). These reports is been supported by a study by McLachlan A *et al*, explains the use of medications analgesics in elderly people is as pain relief and usually men are more prone to administration of pain killers than men.[103]

When the educational Status Distribution among the participants was considered 175 (46.42%) participants were having high school level of educational status (Table 3, Figure 3). The monthly income of the participants was also considered and it was found that out of 377 participants 204 of them came under the category upper lower level and 121 participants fell under the category lower category (Table 4, Figure 4).These parameters

was analyzed in this study as previous studies reveals that lack of educational status was the major cause of paracetamol misuse in those population, and it was supported in a study conducted by Christina J[104] *et al*.

Among the population of the present study, the reason for use of paracaetmol was accessed and it was found that the 159 participants used paracetamol due to headache, 88 of them due to fever, 73 of them due to any kind of arthralgia and 57 due to cold and cough (Table 5, Figure 5). These findings was supported by Alan D *et al,* where a review was conducted to find out the distribution of paracetamol in elderly people and it was founds that paracetamol was the most used drug as pain relief in elderly.[105]

Dosage form purchased among the participants was taken into concern and it was found that Tablet form of paracetamol was purchased the most by 291 participants and 86 of them purchased the liquid form of the medication. (Table 6, Figure 6). Tablet dosage form was the maximum used as the participants were majority of adults.

In order to check the knowledge about the medication among the participants, the participants was asked about the drug and 301 participants admitted that they have knowledge about the medication. (Table 7, Figure 7). And out of these 301 participants, they were asked about the available strength of paracetamol in the market, a maximum of 179 participant marked 500mg as the answer followed by 149 participants admitting 650mg of paracetamol is available in the market. (Table 8, Figure 8). Compared to the knowledge assessment of participants about the oral form of paracetamol only 140 participants admitted that they have knowledge about the liquid form of paracetmol (Table 9, Figure 99). Among these 196 participants 83 participants admitted that 500 mg/5 ml is the dose available in the market while participants 76 participants admitted that 250 mg/5 ml is the dose strength which is available in the market. (Table 10, Figure

10) The majority of participants in this study were well known about the doses available in the market.

Knowledge about Number of doses of paracetamol that can be taken per day was assessed from these 377 participants and the majority (137 participants) reported as they don't know how much number of doses of paracetamol can be taken per day while 101 participants mentioned as 2 doses, 74 participants mentioned as 1 dose, 38 participants mentioned as 3 doses and 27 participants mentioned as 4 doses. This clearly marks that the participants were not aware about how many doses of paracetamol can be taken per day. (Table 11, Figure 11) and to get the accuracy of their knowledge about the paracetamol drug, they were asked what could be the minimum time between each dose of paracetamol and it was surprisingly found that out of 377 participants 227 were unaware about the time gap between each doses (Table 12, Figure 12). In this study, the knowledge of maximum single dose was accessed and it was found that 127 participants opted 0.65g as the maximum single dose. The knowledge of maximum daily dose was also accessed from the participants and it was found that 2g was opted by 99 participants. These results are shown in Table 13 and Table 14 respectively.

According to WHO, the safe dose of paracetamol for adult was 500mg to 1 gram, which is required after 4 – 6 hours and the maximum 4 dose during a day can be taken (2 – 4 g per day), the safe dose for childrens aged 12- 16 years is 480 -750mg which is required every 4-6 hours, a maximum of 4 dose during days and the safe dose for those aging 10-12 years is 480 – 500 mg which required after every 4-6 hours, maximum 4 dose during a day.[106]

In order to check whether the participants were aware about the harmful effects of the excessive use of paracetamol, their knowledge was accessed and it was found that 237 participants were known, out of which 76 of them had the knowledge of hepatic toxicity caused due to paracetamol. These results are shown in Table 15 and Table 16 respectively.

To evaluate further knowledge of the participant about the drug paracetmol, they were asked whether paracetamol is safe to use with other medication and whether paracetamol is safe to use during pregnancy, and the results showed 310 participants were well known about the drug interactions while 198 participants admitted their knowledge of paracetamol is safe to use during pregnancy (Table 17 and Table 18). This present study shows the importance of informing the public that use of paracetamol during pregnancy especially during the third trimester, may be causally involved in decreasing hematopoietic stem cells in cord blood this was supported in a study which was conducted by Lars B[107] *et al*.

In Table 19, it shows the distribution of how the medication paracetamol is been recommended to the participants, and it is seen that 235 of them was recommended to paracetamol by their friends and Table 20 represents out of 377, 287 of the participants recommended paracetamol to other friends.

In this study it was checked whether the patients were aware about harmfulness caused due self-medication and surprisingly 211 participants were aware still they misused the paracetamol use, the same was in the case when the participants was questioned about the safety of using paracetamol under the age 6, 223 participants admitted that they knew that use of paracetamol under the age 6 is unsafe (Table 21, Table 23). WHO recommends the use of paracetamol under 6 years safe until and unless the proper dose is preferred for the

child according the age group. For new borns (3-6 months) the recommended dose is 2.5 ml, for infants (6-24 months) the recommended dose is 5 ml, for childrens aged 2 to 4 years the recommended dose is 7.5 ml and for children from age 4- 6 years the recommended dose is 10ml, the required time interval is 4-6 hours and maximum 4 doses in 24 hours.[108]

In this study it was noted that medication paracetamol was purchased by 168 participants for self-use, 112 participants for caregivers and 97 participants brought the medication for their childrens. (Table 22)

Since childrens and elderly was included in the administration of the medication, their knowledge on the measuring devices used for administrating syrups was accessed and it was found that 152 participants were well known about the use of droppers while 147 had a good knowledge of standard cups for measuring the liquid dosage form paracetamol (Table 24).

To assess the further knowledge about the medication in the participants, they were asked how many of them checks the expiry date of the medication before administration, how many of them uses the leftover medications and how pills are been purchased at an average in a month, and the report shows that 217 participants ensures the date of expiry before administration of the medication, 227 participants uses the leftover medications and maximum of 186 participants purchases paracetamol medication at a number two pills in a month, these studies shows the safe use of paracetamol among the selected participants (Table 25, Table 26, Table 28).

In order to check whether the participants are getting the enough counseling from the pharmacist at the time of purchase, they were asked what the counseling tips they attain

from the pharmacist at the time of purchase. And this study shows that most of them that is 212 participants got the counseling of how to take the medication considering the diet followed by 102 participants who admitted that they got the counseling about the maximum dose that can be taken in a day (Table 27). Thus it was noted that proper education and awareness of the medication is what led to the misuse or overuse of paracetamol in few of the participants in the study. This was also supported by a study conducted by Maham T[109] *et al,* who conducted a study to assess the prevalence of self-medication, level of awareness and knowledge regarding OTC medicines (specifically paracetamol), 352 university students through structured interview method. And the results of the study offered an indirect assessment of the knowledge among our general population as well as an estimation of misuse related harmful impact of OTC medicines. Moreover, it point out a major knowledge gap, low risk perception and significant prevalence of self-medication with paracetamol among our population, illustrating an increased potential of its adverse effects through overuse or misuse. These finding reveal a substantial need for educational intervention around OTC medicines. This study served as an eye opener for healthcare practitioners who should be proactive in commencing health awareness programs as well as superintending the irrational OTC drug use among public.

Thus, this present study also gives us an insight of the importance of educating the public about the medication paracetamol, proper education and counseling tips should be provided for all age population about the risk and benefits of the paracetamol medication.

7. CONCLUSION

Paracetamol, as all drugs, has desirable and undesirable characteristics. It has benefits related to pain relief and it has risks related to adverse effects. This study reiterates the lack of patient knowledge concerning acetaminophen identification, safe use, and potential risks. Certain issues need to be addressed regarding the OTC use of paracetamol, namely raising awareness of the potential side effects, reason of intake, and the recommended daily dose. Greater education is needed for patients regarding Paracetamol's purpose, the types of products containing Paracetamol, and how to use acetaminophen safely and manage toxicity. During patient contact, pharmacists and prescribers can play an important role in educating patients on the appropriate use of products containing Paracetamol. There must be national education campaigns by health care professionals and drug information centers to inform consumers on the safe use of OTC pain relief products, encouragement of the habits to read instruction given in the leaflet. Future actions should be heading in the direction of recognizing factors that influence consumers' view of analgesics and OTC drugs in general, given that these beliefs are associated with proper use, as well as with over-use. The small sample size of participants from two local community pharmacies in this study limits the generalizability of findings. The surveys also were conducted in busy public areas with relatively more distractions than one may encounter in the privacy of one's home. In addition, whether survey participants differed from those who declined to participate is unknown. Therefore, one should not interpret findings from this study as representing a national sample of patients.

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JKKN
College of Pharmacy

J.K.K.NATTRAJA ETHICS COMMITTEE
J.K.K.NATTRAJA COLLEGE OF PHARMACY

(MANAGED BY J.K.K.RANGAMMAL CHARITABLE TRUST)
Natarajapuram, NH-544 (Salem to Coimbatore),
Komarapalayam -638 183, Namakkal District, Tamil Nadu.

Ref: JKKNCP/ETHICS_PRACTICE/018PDS05 ***Date: 17.07.2017***

To
Dr. R. Sambath Kumar, M.Pharm, PhD.,
Department of pharmaceutics,
J.K.K. Nattraja College of Pharmacy,
Kumarapalayam – 638183,
India.

Dear Sambath Kumar,

The proposal entitled **"CONSUMERS' KNOWLEDGE AND USE OF PARACETAMOL (ACETAMINOPHEN) IN OVER-THE-COUNTER MEDICATIONS"** was reviewed by the ethics committee in its meeting held on 17.07.2017 and permission is granted to you to carry out the study.

Thanking you,

Yours faithfully,

Dr. A. Sivakumar
Chairman of Ethics Committee

PRINCIPAL
J.K.K.NATARAJA DENTAL
COLLEGE & HOSPITAL
KOMARAPALAYAM - 638183

INFORMATION FOR PATIENT

Dear participant,

I **Mr.MUHAMMED SHARKY .A, [REG.No.261640206]**student of **J.K.K.Nattraja College of Pharmacy, Kumarapalayam** currently conducting a project entitled **"Consumers' knowledge and use of Paracetamol (acetaminophen) in over-the-counter Medications"** for the partial fulfillment for the award of Degree of **Master of Pharmacy** in **Pharmacy Practice.**

As the part of project we need to collect data including socio-demographic details, Non adherence, Treatment satisfaction and Medications prescribed from your case sheet.

We will appreciate very much if you could kindly assist us to collect your medical data's. However identifiable personal data's will not be disclosed.

Thank you very much for your kind participation.

CONSENT FORM

I, _____, have read and understand the above information. I have agreed to allow my data to be collected for the project work.

_____ _____

Signature of participant Date

_____

Signature of translator

ANNEXURE – I

1. Name of the patient

2. Address

3. Phone number
4. Age (in years)
    a. < 20
    b. 21-40
    c. 41-65
    d. > 65
5. Gender
    a. Male
    b. Female
6. Educational status
    a. Illiterate
    b. High school level
    c. College level
7. Monthly income
    a. Lower
    b. Upper lower
    c. Lower middle
    d. Upper middle
8. What is the reasons for use of paracetamol ?
    a. Headache
    b. Fever
    c. Cold and flu
    d. Arthralgia
9. Which dosage form you have purchased?
    a. Tablets
    b. Liquid orals

10. Do you know thestrength of paracetamoltablets?
    a. yes
    b. no
11. If yes, what is the strength of tablet?
    a. 100
    b. 250
    c. 325
    d. 500
    e. 650
12. Do you know the strength of liquid orals?
    a. yes
    b. no
13. If yes, what is the strength of liquid orals?
    a. 120 mg/5 ml
    b. 250 mg/5 ml
    c. 500 mg/5 ml
14. How many doses preferred per day?
    a. 1
    b. 2
    c. 3
    d. 4
    e. don't know
15. Minimum recorded time between doses
    a. Correct
    b. Don't know
    c. Inappropriate
16. What is the Maximum strength of single dose?
    a. 0.5 g
    b. 0.65 g
    c. 1 g
    d. 3 g
    e. 4 g
    f. Don't know

17. What is the maximum daily doses of paracetamol?
    a. 0.5 g
    b. 1 g
    c. 3 g
    d. 4 g
    e. 5 g
    f. Don't know
18. Is it harmful to consume too much acetaminophen in one day?
    a. Yes
    b. No
    c. Don't know
19. If yes, what are the types of effects occur due to this drug?
    a. Death
    b. Liver problems
    c. Other problems
    d. Don't know
20. Is it possible to take acetaminophen with other drugs?
    a. Yes
    b. No
    c. Don't know
21. Do you thinkalcoholinterferes the action of acetaminophen?
    a. Yes
    b. No
    c. Don't know
22. Is acetaminophen safe during pregnancy?
    a. Yes
    b. No
23. Source recommendation of paracetamol as OTC medication?
    a. Family
    b. Friends
    c. Advertisement
    d. Doctors only
    e. Internet

24. Do you advice someone to use paracetamol?
    a. Yes
    b. No
25. Do you prefer self prescribing of paracetamol?
    a. Yes
    b. No
26. Status of Medication Users
    a. Own use
    b. Care giver (for Adult)
    c. Care giver (For Children)
27. Do you think paracetamol is a safe medication under 6 years of age?
    a. Yes
    b. No
28. Do you aware of various dosage forms of paracetamol at different age groups?
    a. Yes
    b. No
29. What are the measuring devices available for administrating paracetamolsyrups?
    a. Standard cup
    b. Spoon
    c. Dropper
    d. Other
30. Do you check the expiry date of medication?
    a. Yes
    b. No
31. Have you used expired medications?
    a. Yes
    b. No
32. Is your pharmacist enquiring about the combination of medicines taking with paracetamol?
    a. Yes
    b. No

33. What are the information's given while purchasing paracetamol?
    a. Maximum daily dose
    b. For use with / after meals
    c. To drinking sufficient amount of water
    d. about drugs which should not be combined with ibuprofen
    e. about the cost of medication
    f. About nothing
34. What is the average no. of paracetamol bought in a month?
    a. 1
    b. 2
    c. 3
    d. more than 3